IVD medical equipment

Fluorescent Quantitative Detection system

LineGene 9600 Series

User's Manual

CE

Attention

- Users are recommended to carefully read the contents of this manual before operating the Bioer Fluorescent Quantitative PCR Detection System.
- To carefully observe all special Warnings and Cautions outlined in this manual.
- This manual should be maintained properly in good condition for reference.

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The manual contains copyright protected and patented material. Without prior written consent from Hangzhou Bioer Technology Co., Ltd., any part of the manual shall not be duplicated, reproduced or translated into any other language.

Thank you for your purchase of this product.

Before initial use of this instrument, please carefully read this manual !

File No.: BYQ60840000000ESM

File Version: January ~~August AugustMarch May~~ 2012~~0~~ Version 1.~~.186~~0

Important Notes

1. Usual practice

Announce: Very important information is contained in any item and should be carefully read. Failure to operate instrument according to the instruction would result in damage or abnormal function of instrument.

Warning! The warning message requires extremely careful operation of a certain step. Failure to observe the instruction would result in serious personal injury.

2. Safety

During operation, maintenance and repair of this instrument, the following basic safety notes shall be observed. In case of failure to follow these measures or the warnings or notes indicated herein, the basic protection provided by the instrument, its safety criteria of design and manufacture, and its predicted use range would be impaired.

Hangzhou Bioer Technology Co., Ltd. shall be irresponsible for the consequence resulted from user's failure to observe the following requirements.

Note: The instrument, complying with the Standard GB4793.1/IEC61010-1, is a general instrument of class Ⅰ, the protection degree is IP20. It is intended for indoor use.

Note: The instrument, complying with the Standard YY0648/IEC61010-2-101, is used for IVD medical equipment.

a) Instrument earth

In order to avoid electrical shock accident, the input power wire of instrument shall be reliably earthed. This instrument uses 10A 3-core earth plug and this plug is provided with a third (earth) leg, is merely used for earth type power socket and is a safety unit. If the plug is impossible to insert into the socket, the socket shall be correctly fixed by electrician; otherwise, the earth plug would lose safe protection function.

b) Keeping apart from the live circuit

The operator shall not arbitrarily remove instrument protector, replace elements or make inside adjustment, and the task, if necessary, shall be made by qualified professional maintenance personnel. Replacement of elements under energizing state shall be prohibited.

c) Use of power supply

Before turning on AC power, make the power voltage consistent with the instrument-required one (100-240V~, 50/60Hz) and make the rated load power socket not below instrument's maximum load 600W.

d) Power wire

Generally, this instrument uses accompanied power wire. The damaged power wire shall be replaced by one of the same type and same specification. It can't be repaired. The power wire shall neither be compressed nor be laid in gathered personnel location.

e) Insertion and withdrawal of power wire

At insertion and withdrawal of power wire, the operation portion of the plug shall be correctly held with hand. At insertion, the plug shall be completely and tightly inserted into the socket and at withdrawal heavily pulling the wire shall not be allowed.

f) Placement of instrument

This instrument should not be laid in the place where it is different to cut off the power supply.

This instrument shall be fixed in a low RH and low dust place apart from water source (e.g. water pool and water pipeline) and the room shall be well ventilated, and free of corrosive gas or and interference of strong magnetic field. The instrument shall not be placed in a wet or dusty location and its working table shall be level and steady.

The openings on this instrument are for ventilation circulation and in order to avoid over-head of the instrument body they shall not be blocked or covered. When a single set or several sets of instrument are used, the interval between its surrounding ventilation opening and its nearest object shall not be below 30cm or 50cm.

Excessive environmental temperature would impair the test performance or result in fault of instrument. This instrument shall not be used in location subjected to direct sunshine or strong radiation of light source, otherwise, its fluorescence detection would be impaired. The instrument shall be kept away from hot gas, strove and all other heat source.

At shutdown, the power shall be cut off. If the instrument is to be set aside for a long time, the power shall be cut off, the power plug withdrawn and the instrument covered with soft cloth or plastic film to avoid entrance of dust and foreign matters.

g) Notes during operation

During test, cares shall be taken to prevent liquid from dropping onto the instrument. The castoff used in test , such as consumables, reagent, and so on, should be treated as require, and should not be thrown away or poured.

During test, if there is hazardous substances, user must be trained before using.

Hazardous substances, which has been used, should be coped with and saved according to derection for use.

User, who operates the instrument, must be trained and has relevant quantification.

Caution: In any of the following cases, immediately cut off the power supply, withdraw the power plug from the power socket, contact the supplier or ask qualified repair personnel for treatment:

- Liquid drops into inside of the instrument.
- The instrument is rained or watered.
- The instrument works abnormally, especially generates abnormal sound or odor.

- The instrument is dropped or its casing is damaged.
- The function of instrument obviously changes.

Caution: When you deal with potential contagious matter such as flesh sample or reagent, which is likely to touch skin, protecting glove or other protecting measures are need to be used.

h) Transportation again

If transporting the instrument again, the instrument and its detection wells need be cleared wholely before transportation, and be disinfected by UV light. After clearing, the fixing pin shall be tightened to transportation well when the instrument stops running and power off so that motion componet of the instrumnt interior can be fixed and motion componet is avoided to be demaged during transportation. Introduce of the location from transportation well is seen in chapter of fixing pin backout.

i) Warning Sign~~mark~~

- Warning identification

DANGER!		Place pasted this mark in instrument, is danger, if the instrument is used irrelevancy.
SCALDING!		Place pasted this mark in instrument, causes high temperature and is scalding during use.
BIOHAZARD		Place pasted this mark in instrument, caused biohazard during use.
PROTECTIVE EARTH		Protective earth is near to the place pasted this mark in instrument

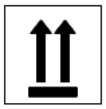
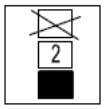
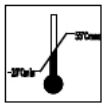
- Warning mark

Warning! The instrument is adhered with mark “HOT SURFACE!” During operation of instrument or a period immediately after completion of running of a program, any portion of body shall not be contacted with metallic portion (module) nearby the said mark; otherwise, skin would be burnt.

Warning! Operator may touch matter which is baneful to organism or is contagious during using instrument. Operate should realize the harmfulness, and operate in the condition which must accord with rules of PCR lab. And operator must be

trained or be provide with qualification.

j) Sign of external packing

Up		Correct position of transport package is vertical upwards.
Breakables		Be treated with care when transportation, there is breakables in transport package,
Fear rain		Transport package is not rained.
The limit of stacking layer		Maximum stacking layer of the same package is 2.
Temperature limit		Temperature limit that transport package should keep is form -20C to 55C.

3. EMC Consideration

Note: This is a class A equipment, only suitable for use in establishments other than domestic, and those directly connected to a low voltage power supply network which supplies buildings used for domestic purpose.

4. Maintenance of instrument

The stained surface of this instrument, if any, shall be cleaned with soft cloth soaked with cleaning paste.
Heat conductive oil medium shall not be used in module holes of this instrument.
Module should be pushed in in time to prevent dust during normal conservation or after use.

Warning!

- At cleaning of instrument, its power supply shall be cut off.
- The instrument surface shall not be cleaned with corrosive cleaning agent.
- Instrument module includes precise optics, dust, foreign matter and residue should be avoided.

5. After-sales services

The warranty content and scope are shown in the warranty sheet.

Note:

- After unpacking, immediately check the goods against the packing list. In case of damaged or missed goods, please immediately contact the supplier.
- After qualification of acceptance, properly fill the product acceptance sheet and send (or fax) the copied sheet to the supplier for filing and maintenance.
- Before use of the product, the user shall feedback the information registration table to Hangzhou Bioer Technology Co., Ltd. and obtain correct operation password.
- After unpacking, the packing box and packing materials shall be well kept for future repair.
- The instrument should be disinfected before sent to the repair department.
- Fixing pin must be fixed correctly as manual before transporting instrument.
- Maintainer must disinfect the instrument immediately after unpacking when instrument is sent to repair department.
- For the damage of instrument occurring during transporting to the repair department due to improper package or incorrect place of fixing pin, Hangzhou Bioer Technology Co., Ltd. shall bear no liability.

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Chapter 1 General description

This chapter mainly describes the applications, features, specification, model, performance parameters and software function of 96-well Fluorescent Quantitative Detection System.

1. Applications

96-well fluorescent quantitative PCR detection system adopts amplification of fluorescent real-time detection mode analysis PCR module and is suitable for polymerase chain reaction fluorescent quantitative detection in research fields of human genome engineering, forensic, cancer, tissue, population biology, paleontology, zoology and botany and in clinical diagnosis of virus, cancer and genie diseases.

PCR detection system belongs to IVD medical equipment, which is to use polymerase chain reaction means to quantitative analysis of different genes in clinic lab.

2. Features

- Novel and human-orientated running and operation interface make operation much smooth.
- The adopted fluorescent real-time detection mode realizes simultaneous amplification and detection in a same tube without need of post treatment.
- Advanced thermoelectric refrigeration technology ensures fast and steady heating and refrigerating of ultra-fast heat cycles system.
- Multi-point temperature control ensures much even temperature of 96 sample holes.
- It can control the temperature gradient of 4 areas through setting.
- Stable and correct 1～36°C gradient function makes PCR condition optimal.
- The constant temperature function of SOAK realizes low-temperature storage of PCR reagent.
- It uses maintenance-free LED excitation light source of long service life.
- The advanced optic fiber transmission technology makes photo-electric detection system much sensitive and reliable.
- Precise optical path system and ultra-sensitive PMT system render best correctness and sensitivity of fluorescent detection.
- It can make real-time dynamic monitor of the entire PCR amplification process.
- It has high linear range up to 10 orders of start DNA copies without gradient dilution.
- PCR reaction tube is unnecessary to open, which protects products during and after PCR from contamination and ensures correct results.
- The multi-color fluorescence monitor may acquire much information from a single reaction.
- The hot-lid technology realizes oil-free operation of PCR.
- Automatic hot-lid technology needs no manual opening/closing and ensures constant pressure of hot-lid used in different-high test tube.
- It has full-Chinese interface and the functions of flexible setting of program and overall analysis and report and can store all parameters.
- It can print out several or a single sample report.

- Automatic, correct and timely remote networked services provide 96-well quantitative detection system the latest technical support.
- The advanced module bottom fluorescent detection technology is protected by invention patent.

3. Notes to model and description

Model:

FQD – 96 A

- A: Design series number
- 96: Specification code, 96 denoting maximum sample quantity 96
- FQD: Abbreviation for Fluorescent quantitative polymerase chain reaction (PCR) detection system

Description:

LineGene 96 ××

- ××: Code of ray filter pack
  - 20 （with ray filter of F1，F2）
  - 40 （with ray filter of F1，F2，F3，F4）
  - 60 （with ray filter of F1，F2，F3，F4，F5，F6）
  - 80 （with ray filter of F1，F2，F3，F4，F5，F6，F7，F8）
- 96: Specification code, 96 denoting maximum sample quantity 96
- LineGene: English name of description of Bioer Fluorescent quantitative polymerase chain reaction (PCR) analysis system series.

4. Performance parameters

Specification/ model	FQD-96A							
Sample capacity	96×0.2ml (suitable for single tube, 8-row tubes and 96-well full-apron plate)							
Detection channel	F1	F2	F3	F4	F5	F6	F7	F8
Applicable dye	FAM, SYBR Green I	VIC, HEX, TET, JOE	Cy3, 5-TAMRA, NED	ROX, TEXAS-RED	Cy5	Light Cycler Red Quasar705	-	-
Temperature range of block working	4～105°C (Minimum division:0.1°C)							

Heating/cooling	4.0°C/s (max)

rate	
Temperature fluctuation	≤±0.1°C (full-range), (55°C typical value ≤±0.1°C)
Temperature accuracy	≤±0.2°C (full-range), (55°C typical value ≤±0.1°C)
Temperature uniformity	≤±0.4°C (full-range), (55°C typical value ≤±0.3°C)
Temperature range of hot-lid working	30～110°C (adjustable, default 105°C)
Repeatability of fluorescent intensity detection	5%
Running mode	Continuous running
Operation system	Windows2000/XP/Windows Vista/Windows7
Power supply	100-240V～ 50/60Hz 600W
Dimensions	430mm×395mm×352 mm
Weight	28kg

Caution: F7 and F8 are the preserved dummy channels and may be customized as per actual requirements of customers.

5. General description of functions of the necessary software

a) Parameters setting-up function (including temperature, time, cycles, heating/cooling rate, selection of detection channel and yield of photo-electric amplification tube)
b) Note function of text contents
c) Sample material record function (sample No., sample name and sample data)
d) Document running display function (PCR heat cycle data display, fluorescence detection data display and real-time display of each data during running of instrument)
e) Detection data analysis function (The analysis function may be independently used under no connection of instrument)
f) Analysis result output function (It may output the analysis result to other type document, e.g.: EXCEL, TXT document, it can inquiry and print out analysis result, modify printing format and select printing items.)
g) Document storage function (setting up data, running data and analysis result)
h) Trouble protection and alarm function

Caution: The above-mentioned software function is merely for reference. The software function would be modified without notice.

Chapter 2 Preparations

This chapter mainly describes use, transport and storage condition, structural composition, removal of fixing pin, installation/unloading of software and preparations before start of LineGene 9600 series fluorescent quantitative detection system.

1. Transport and storage condition of instrument

Environmental temperature: - 20°C～55°C
Relative Humidity: ≤80％

2. Normal working condition

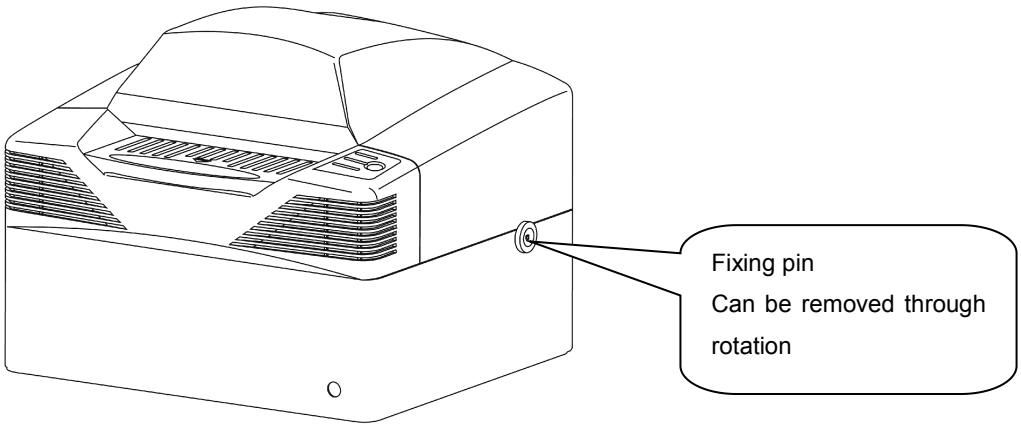
Environmental temperature: 10°C～30°C
Environmental RH: ≤70％
Power supply: 100-240V～ 50/60Hz 600W

Caution: Before use the instrument, please make sure the working condition meets the above requirements. The power socket shall be 3-holesocket and reliably earthed.

3. Preparations before start of instrument

3.1 Removal of fixing pin

In order to prevent the inner moving parts from shift and collision during transport, before leaving the factory they are fixed with fixing pin. After the instrument is placed on the desired location, the fixing pin shall be taken out through counterclockwise rotation, inserted to unlocker hole at its back, and fully tightened to release protection of the inside protective switch. Only after correct installation of the fixing pin, may the instrument be energized; otherwise, the instrument's temperature control system is able to run but X-Y axis scanning system doesn't run.



Please keep the fixing pin tightened. Before moving instrument, turn on the power, pending

completion of self-test action ,then shut down instrument normally and take out the fixing pin, insert it into right hole of instrument and tighten it.

3.2 Connection of power wire and communication wire

Connection of power wire: The instrument-accompanied power wire should be used. At connection the instrument power switch shall be at "OFF" state and after connection the power wire shall be checked for tight contact with the instrument socket; otherwise it shall be replaced.

Connection of communication wire: The accompanied communication wire and communication conversion box shall be used. One end of the communication conversion box shall be connected with DB15 communication interface at instrument back and another end connected with computer USB interface or RS232C interface or Bluetooth interface. After connection, screws shall be surely tightened.

Caution: The accompanied power wire is reliable, but after several times of insertion and withdrawal the connection would likely become loose. In this case, the power wire shall be replaced with the one of same type and same specification.

The communication conversion box is built with special circuits and shall not be arbitrarily opened without permit.

4. System Installation and Unloading ~~of necessary software~~

4.1 System Installation

System Environment

- Operating system: Windows XP/Windows VISTA/Windows7
- Runtime environment: Net Framework 4.0
- Other software: PDF reader

Minimum configuration:

- Processor: Intel Core i3
- Memory: 2GB
- Hard Disc: 10GB

System installation

Double click LineGene9600 installation file (LineGene9600DiagnosisSetup.exe) ▶display the installation interface (select installation language) ▶ set up installation path ▶install

Operating system

- Double click the LineGene9600 shortcut on the desktop
- Click the start menu▶Program▶ LineGene9600

4.2 System Unloading

Control Panel▶Add/Delete Program▶ LineGene9600▶Unload

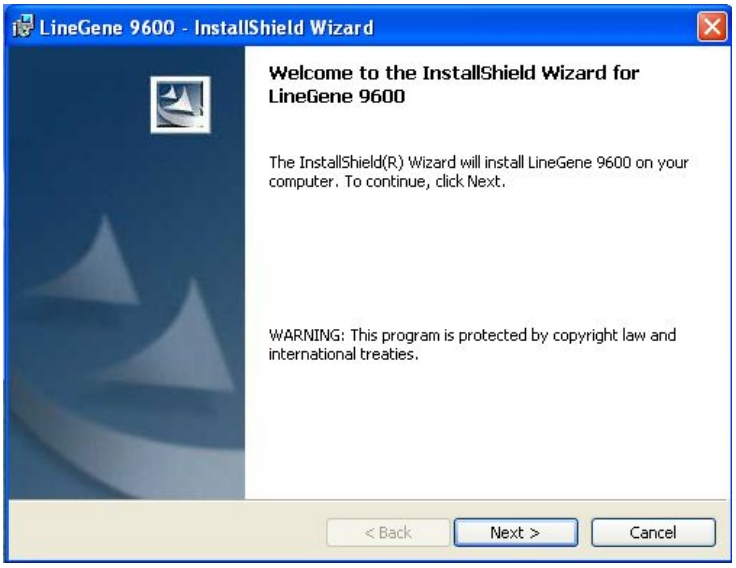
Selection of computer system

Minimum configuration:
Operation system: Windows 2000/XP/Windows Vista/Windows7（English professional or ultimate）
Application software: Microsoft Excel2000/2002/2003,/2007
Microsoft Access2000/2002/2003/2007
EMS memory: 512M
Hard disk: 10G
CPU: Pentium® 4
System setting up: virtual internal mummery above 1000MB

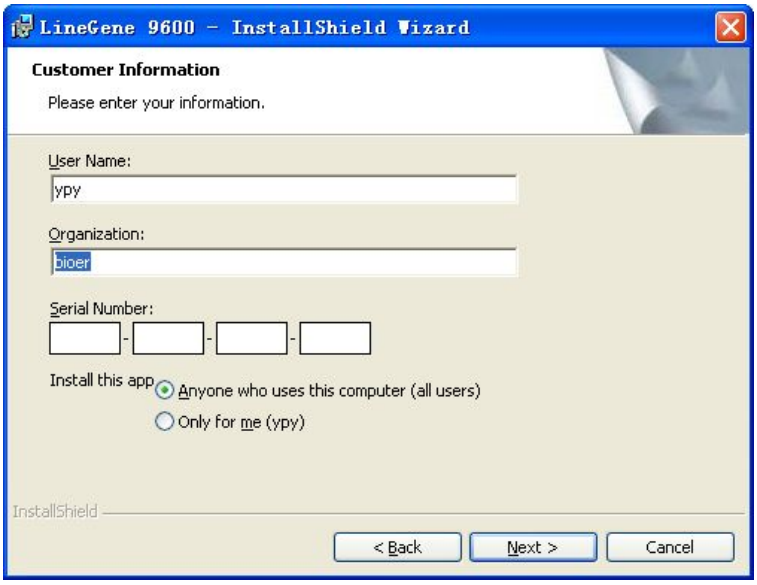
Installation of LineGene 9600 software

After computer starting Windows2000/XP/Windows Vista/Windows7system, insert the installation compact disk marked "LineGene 9600" into optical drive, open compact disk, enter LineGene 9600 folder, double click setup.exe under this directory and enter language selection installation interface of LineGene 9600 fluorescent quantitative detection system software:

After selection of installation language click "OK" to enter the next interface:


LineGene 9600 - InstallShield Wizard
Welcome to the InstallShield Wizard for LineGene 9600
The InstallShield(R) Wizard will install LineGene 9600 on your computer. To continue, click Next.
WARNING: This program is protected by copyright law and international treaties.
< Back
Next >
Cancel

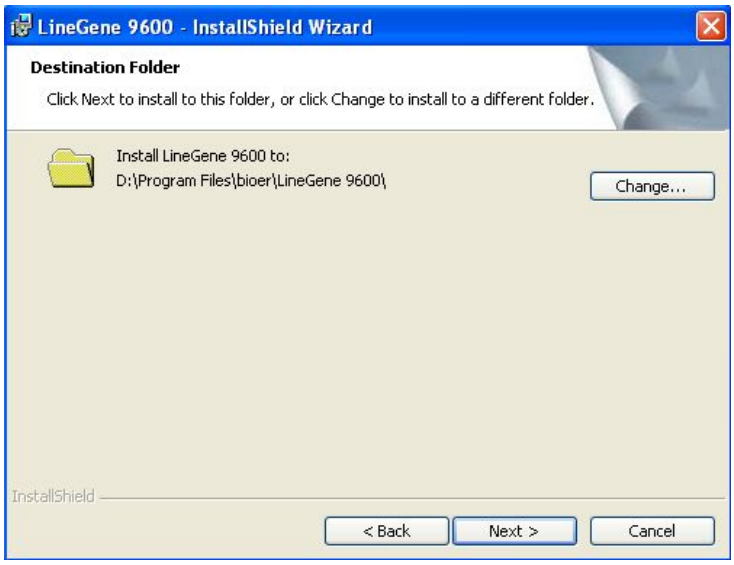
Click "Next >" and enter the next interface:



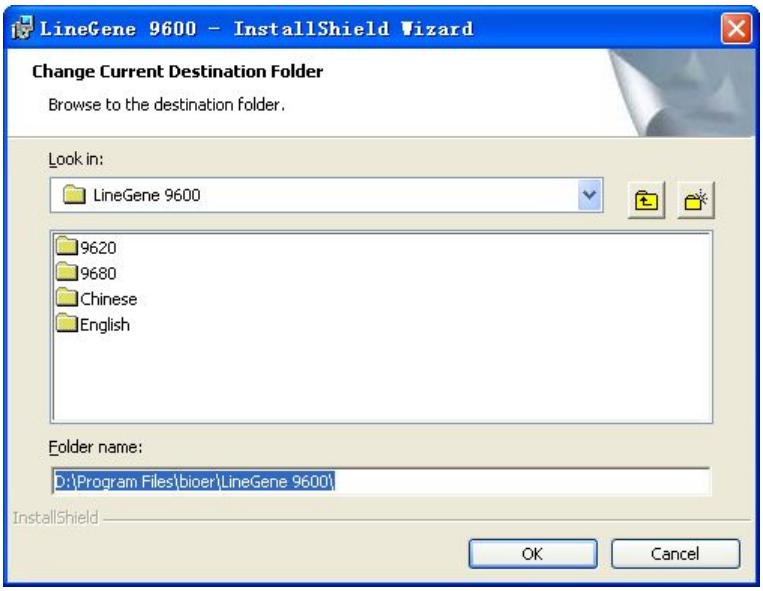
Please input corresponding column: user name, organization and series number.

Caution: *The installation series number of software is shown on the label on front of installation compact disk of LineGene 9600 Fluorescent Quantitative Detection System.*

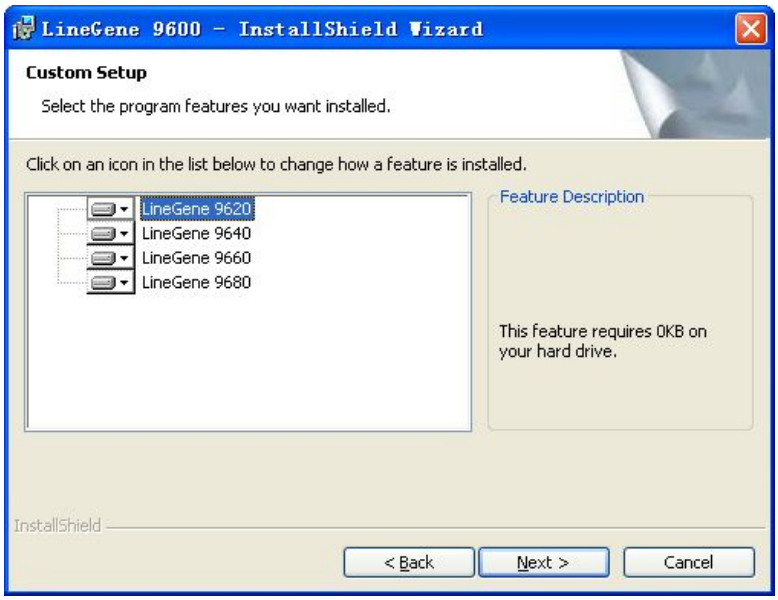
Click "Next >"and enter the following interface:


LineGene 9600 - InstallShield Wizard
Destination Folder
Click Next to install to this folder, or click Change to install to a different folder.
Install LineGene 9600 to:
D:\Program Files\bioer\LineGene 9600\
Change...
InstallShield
< Back
Next >
Cancel

The screen displays installation target position (installation directory). The default installation directory is C:\Program Files\bioer\ LineGene 9600\. For confirmation of the said installation directory, click "Next >" and for modification or new establishment of installation directory, click "Change…" and enter the following installation directory selection interface:



On selection interface of the installation directory, from column "Search range " select the desired installation route or from the column "Folder name" directly input or modify the installation target position, then click "OK", successfully establish route target position and enter "Custom Setup" interface. Select the program which you want to install.


LineGene 9600 - InstallShield Wizard
Custom Setup
Select the program features you want installed.
Click on an icon in the list below to change how a feature is installed.
LineGene 9620
LineGene 9640
LineGene 9660
LineGene 9680
Feature Description
This feature requires 0KB on your hard drive.
InstallShield
< Back
Next >
Cancel

Select the program which you want to install, click "Next>" enter automatic installation. After installation, LineGene 9600 series fluorescent quantitative detection system short-cut icon (Which you selected.) will be automatically formed on desktop:

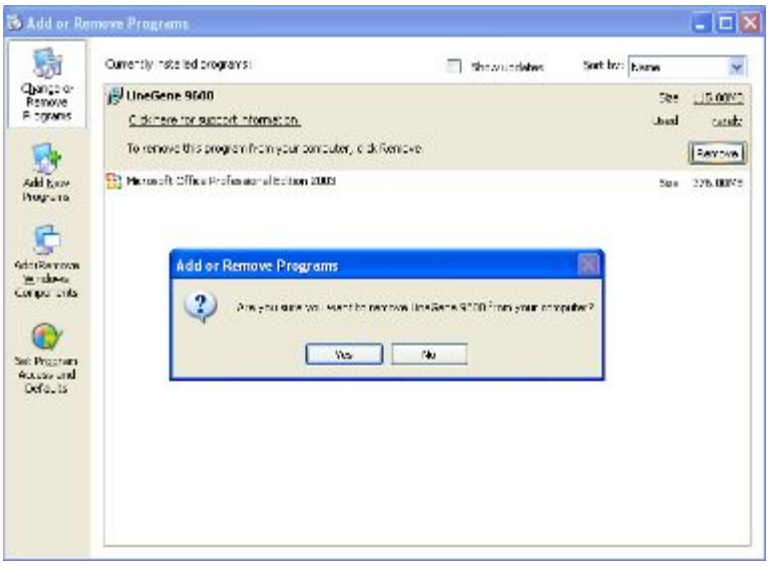
Only channels F1,F2 are allowed with LineGene9620.

Only channels F1,F2,F3,F4 are allowed with LineGene9640.
Only channels F1,F2,F3,F4,F5,F6 are allowed with LineGene9660
All channels are allowed with LineGene9680

Selection of software installation depends on detection channels of instrument. When installation, you should select assorted software according to description of instrument.
After instrument is connected with computer successfully, there are description and number in the status bar, in which usable detection channels are displayed.
*Caution1:All files of modification parameter are saved in folder "AttachedFiles\LineGene9600_******" of root directory of disk. When user installing software, all files of modification parameter are copied automatically in installation directory.*
***Caution2**: After installing the software on the computer without connected to instrument, before analysising the data,please copying default.ser file from the computer connected with instrument to the computer without connected with the instrument (the default .ser file was automatically generated by the computers connected with the instrument). If do not do this,data can't be analysed correctly.*

Unloading of LineGene 9600 software

In [Start]/ [Setup]/ [Control panel] menu click the "Add or Remove programs".
From the "Add or Remove programs" dialog box, click the selection of "LineGene 9600" installation program and click "Remove" key.



Click "Remove" key and on the pop up "Add/Remove program" dialog box click "Yes". The system will automatically uninstall the selected software.
When uninstalling program normally, log files of detection rusult are not deleted automatically. If customer confirms that they do not need these files, they may delete them automatically.

Chapter 3 Start

Caution: Before initial use of this instrument, correctly take out the fixing pin on its side and insert and tighten the lock into unlocker hole at its back; otherwise, the instrument would be unable to make fluorescence scanning (For removal of fixing pin, refer to chapter II, “3.1 Removal of fixing pin”).

1. Checks before start

After inserting the power plug and energizing this detection system, the followings shall be checked:

- Check the voltage of power supply for consistency with system-required one.
- Check the power wire plug for correct and reliable insertion to power socket.
- Check the communication converter for correct insertion into the host and tightening and the lead plug for correct and reliable connection to the computer.
- Check the update shift switch MODE of communication converter for being at normal state.
- Check the environmental working environment and the storage condition for meeting requirements.

2. Start

In order to ensure effective communication connection between the instrument and the computer system, the system shall be started in the following sequences:

1st step: Start computer display and host.

2nd step: Turn on power switch on instrument’s rear bottom board.

3rd step: Press Run Switch on front cover to set the system at running-allowable state.

4th step: After entering operation system, start LineGene 9600 fluorescent quantitative detection system.

For starting software, click “LineGene9620~~0/LineGene9640/LineGene9660/LineGene9680~~” from [Start]/ [program] menu or double click short-cut icon on desktop.

3. Starting software interface

~~Click one of the short-cut icons “LineGene 9620 / LineGene 9640 / LineGene 9660 / LineGene 9680" on desktop, the computer screen will show the following start image.~~

Fig. 3-1 Starting software interface

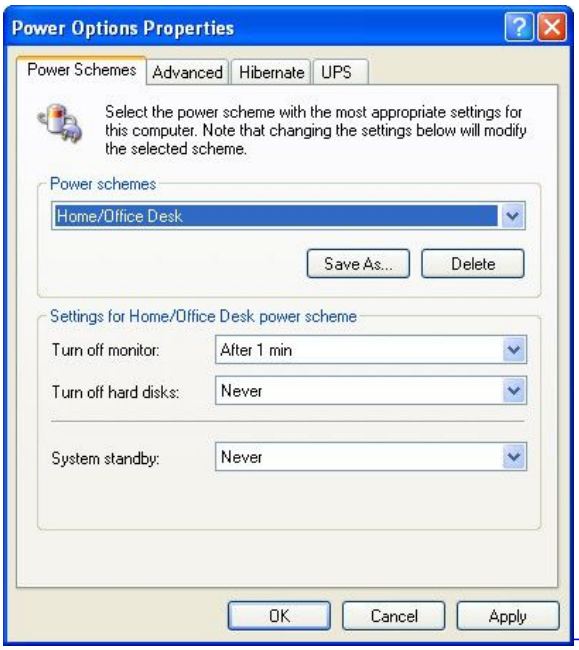
On the starting software interface, there are 4 buttons: Absolute Quantification, SNP, Relative Quantification and Quit.

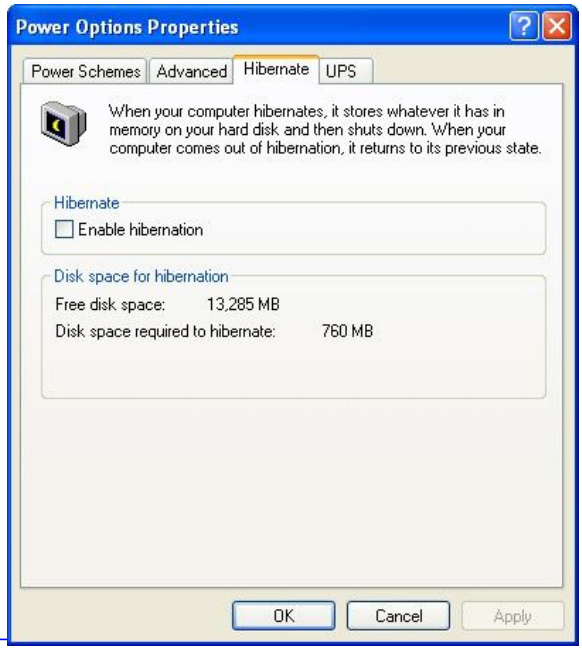
Click “Absolute Quantification”, “SNP” and “Relative Quantification” button to make program enter corresponding detection program setup interface.
Click “Quit” button, close Starting software interface and exit program.

If you are still in one function module and you want to select another, it will not be available. For example, if you are running the absolute quantification, and you click "Relative Quantification", you will get a message as follows:

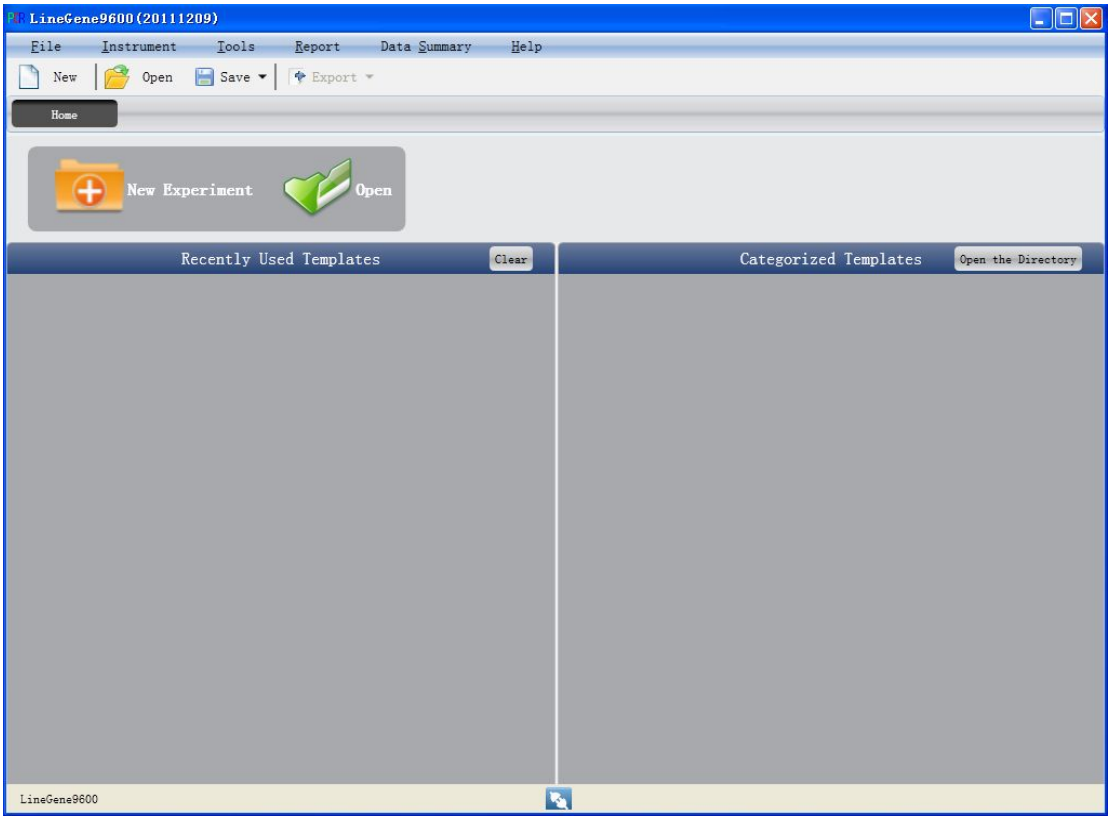
Fig. 3-2 Prompt dialog box

Note: Before doing experiment, please confirm first the computer hibernation state settings and hard drive state settings after opening the computer.
Setting method as follows: righ-click anywhere on your Desktop, select Properties, and click the Screen Saver, and then click the Power Button.
As below chart "Power Schemes", choose "Never" in the closed state of hard drive, and in hibernation, delete the hook before "Enable Hibernation" box.




Power Options Properties
Power Schemes
Advanced
Hibernate
UPS
When your computer hibernates, it stores whatever it has in memory on your hard disk and then shuts down. When your computer comes out of hibernation, it returns to its previous state.
Hibernate
Enable hibernation
Disk space for hibernation
Free disk space: 13,285 MB
Disk space required to hibernate: 760 MB
OK
Cancel
Apply

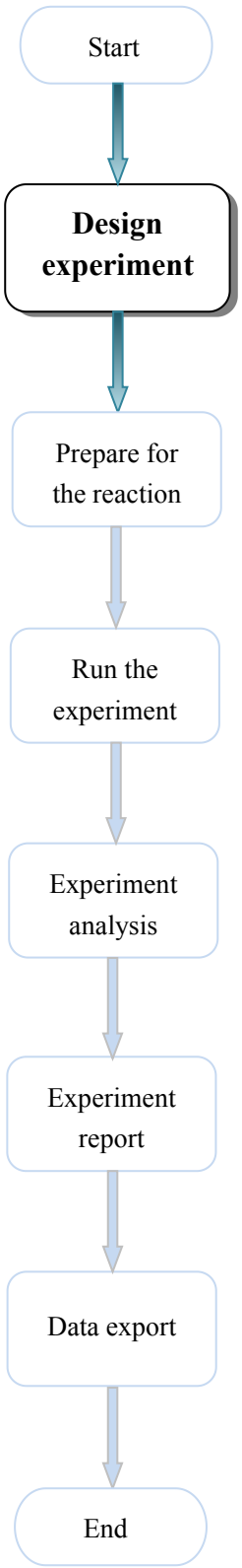
Run the program and it will display the system window.



The system window consists of the menu bar, the toolbar and the main form.

Chapter 4 Absolute Quantification

1. Design Experiment



This section describes how to design absolute quantitative experiment and covers new absolute quantitative experiment, inspection item setting, sample information setting, reaction plate setting and program setting.

This chapter details the establishment, editing, saving, modification, running and analysis of absolute quantification detection program file of LineGene 9600 series

fluorescent quantitative real-time PCR detection system

To build a new absolute quantification detection program file

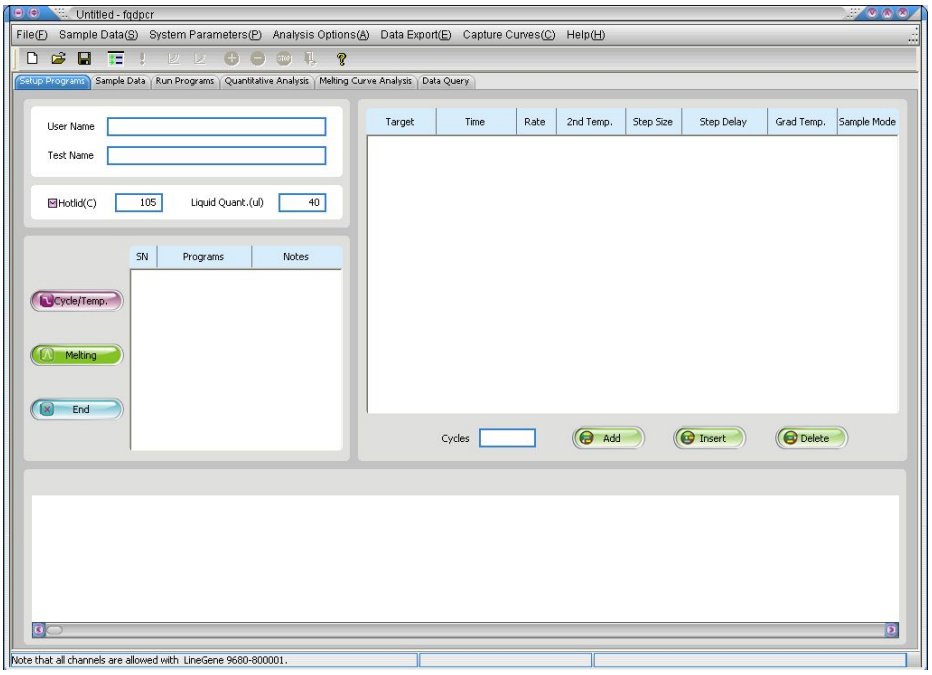
Before newly building a detection program file, click “ ” to open program setup guide, which may give help in completing each setup before running.

The methods to build a new absolute quantification detection program file mainly include the followings:

After clicking “Absolute Quantification” button of “Starting software interface” (refer to Fig. 3-1), the system will automatically open a blank absolute quantification program setup interface (as shown in Fig. 4-1).

After clicking “ ” from “Setup Program” interface of detection file a blank “Setup Program” interface will occur.

Open “File (F) →new (N) Ctrl+N” to establishment a new blank “Setup Program” interface.



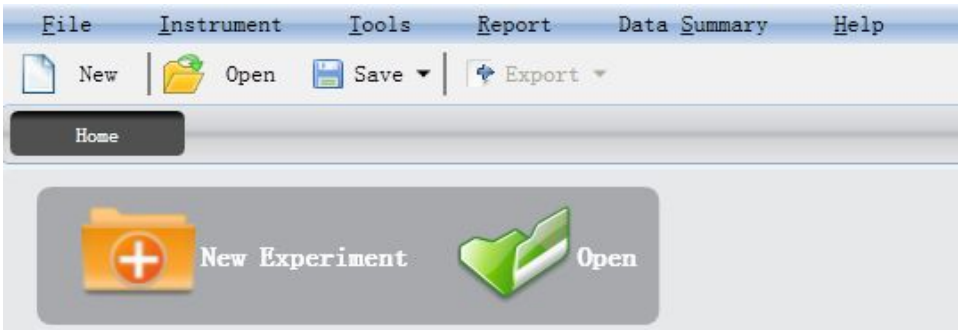
Open interface of blank absolute quantification detection file1.1 Create New Absolute Quantitative Experiment

Click build **New Experiment** on **Home** interface and create absolute quantitative experiment window.

※Absolute quantitative experiment can be also created by:

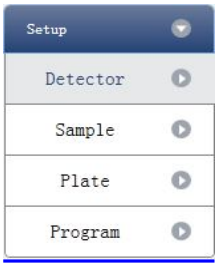
a. Clicking **File**▶**New** on the menu bar

b. Clicking **New** on the toolbar



1.2 Detector Setting

- Click Setup▶Detector



- Input experiment properties

Input the experiment name, user name and comment at the experiment properties column.

- Detector Setting

Set up the Detector, Assay, Dye and Color.

※If necessary, the user can also:

a. Add detector

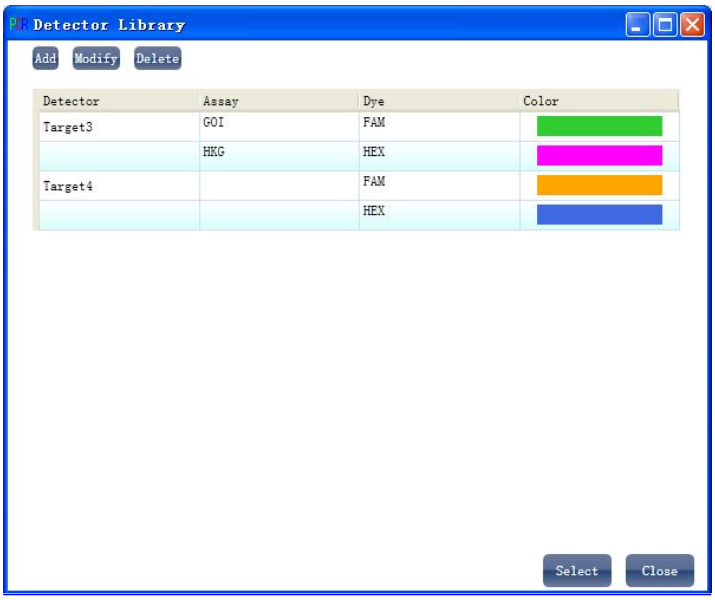
b. Add assay

c. Delete detector

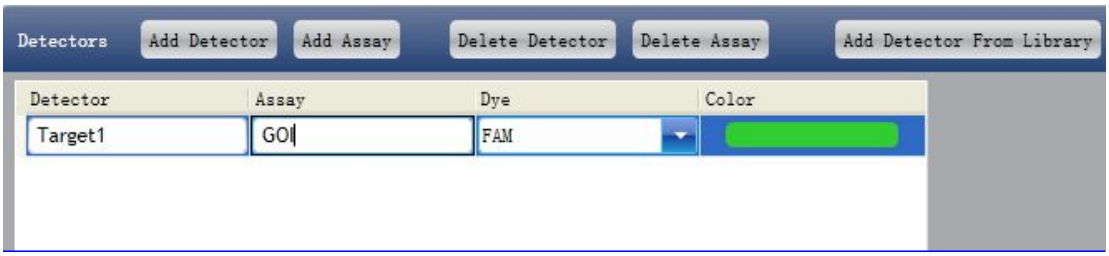
d. Delete assay

e. Add the detector in the Detector Library: click **Add Detector Form Library**▶the **Detector Library** window will pop up▶select the Detector on the window to be added

※The user can also conduct Add, Modify and Delete operations in the item library.



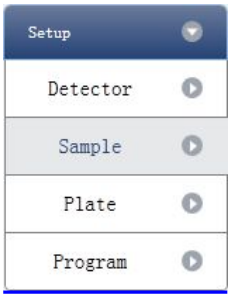
f. Set up the detector, set up the assay, set up the dye name and set up the color



- Set up reference dye

1.3 Sample Information Setting

- Click **Setup**▶**Sample**

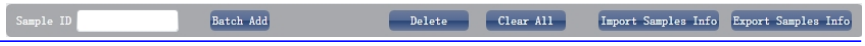


- Add sample information

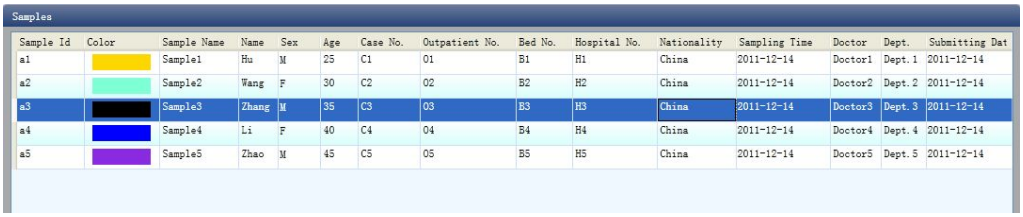
a. Itemized addition: input ID in **Sample ID**▶press **Enter**▶add one piece of sample information

b. Batch addition: click **Batch Add**▶the Batch Add window will pop up

- Delete sample information
  a. Itemized deletion: select one sample ▶ click **Delete** ▶ delete the selected sample information
  b. Delete all: click **Clear All** ▶ delete all sample information
- Import/Export sample information
  a. Click **Import Sample Info** ▶ the File Import window will pop up ▶ import sample information file in CSV format
  b. Click **Export Sample Info** ▶ the Save As window will pop up ▶ the sample information will be exported in CSV file format

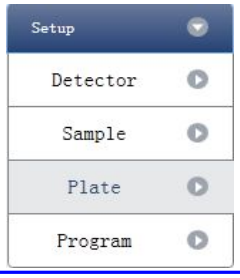


- Set up sample information


Samples
Sample Id
Color
Sample Name
Name
Sex
Age
Case No.
Outpatient No.
Bed No.
Hospital No.
Nationality
Sampling Time
Doctor
Dept.
Submitting Dat
a1 Sample1 Hu M 25 C1 01 B1 H1 China 2011-12-14 Doctor1 Dept. 1 2011-12-14
a2 Sample2 Wang F 30 C2 02 B2 H2 China 2011-12-14 Doctor2 Dept. 2 2011-12-14
a3 Sample3 Zhang M 35 C3 03 B3 H3 China 2011-12-14 Doctor3 Dept. 3 2011-12-14
a4 Sample4 Li F 40 C4 04 B4 H4 China 2011-12-14 Doctor4 Dept. 4 2011-12-14
a5 Sample5 Zhao M 45 C5 05 B5 H5 China 2011-12-14 Doctor5 Dept. 5 2011-12-14

1.4 Reaction Plate Setting

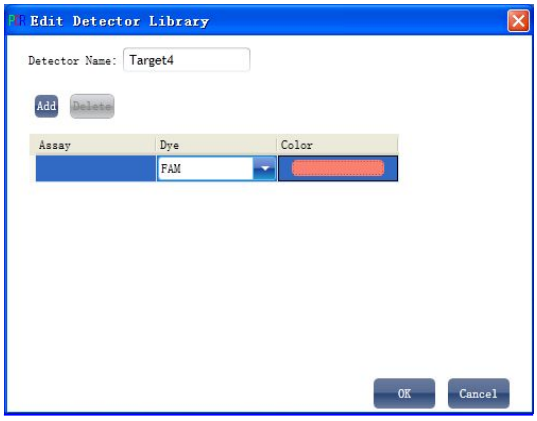
- Click **Setup** ▶ **Plate**



- Set up the inspection items of reaction plate

a. Select reaction plate hole site: click Reaction Plate Hole Site

Apart from reaction plate hole site, the user can also right click the reaction plate hole site to Copy, Paste and Add New Detector. Adding new detector will open the **Edit Detector Library** window.



b. Select Assay item and modify the property, concentration and concentration unit.

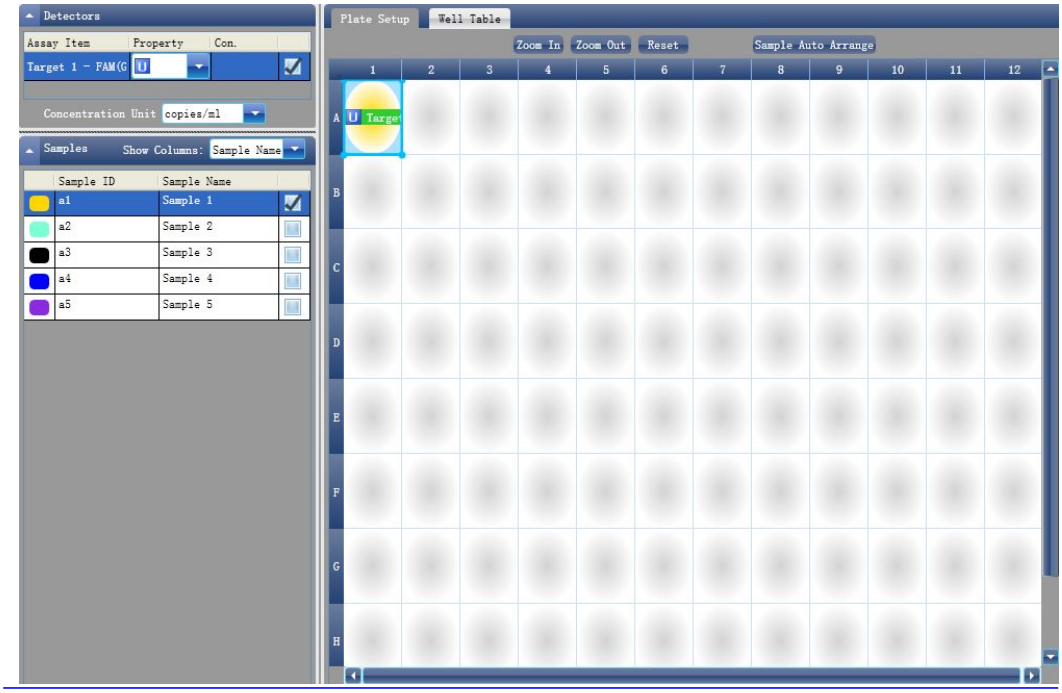
Property	Name	Concentration	Concentration unit
U	Unknown	NO	Copies/ml
S	Standard	YES	IU/ml
N	Negative	NO	Fg/ml
P	Positive	NO	Pg/ml

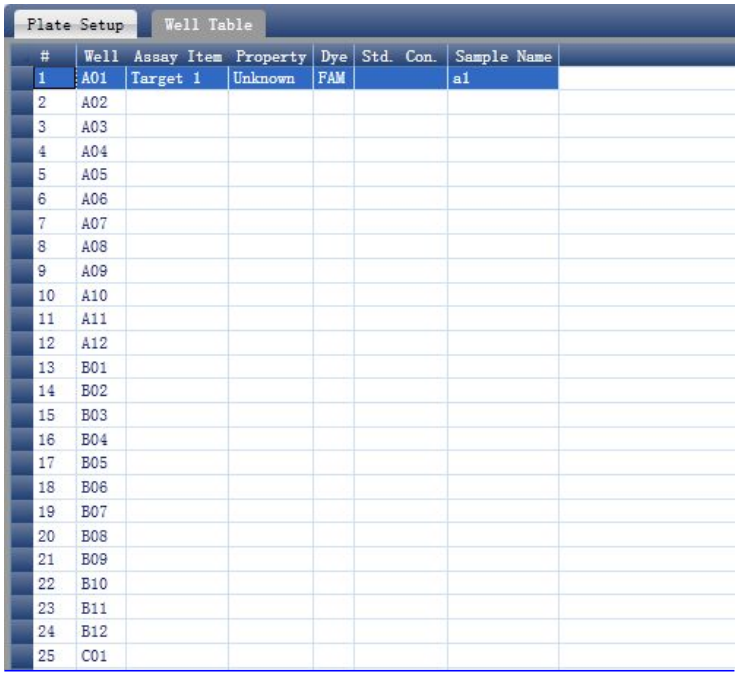
c. Select a sample and the list displayed will change

d. Zoom In, Zoom Out and reset the reaction plate.

e. Sample Auto Arrange

f. Check Well Table

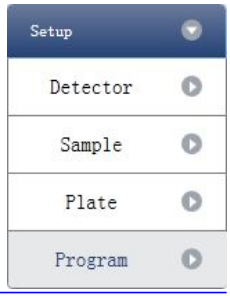




#	Well	Assay Item	Property	Dye	Std. Con.	Sample Name
1	A01	Target 1	Unknown	FAM		a1
2	A02					
3	A03					
4	A04					
5	A05					
6	A06					
7	A07					
8	A08					
9	A09					
10	A10					
11	A11					
12	A12					
13	B01					
14	B02					
15	B03					
16	B04					
17	B05					
18	B06					
19	B07					
20	B08					
21	B09					
22	B10					
23	B11					
24	B12					
25	C01					

1.5 Program Setting

- Click **Setup▶Program**



- Run Programs Setup

a. Create new stage: the user can create new **Hold Stage**, **Cycling Stage** or **Melting Stage**

※ The user can also click **Add Stage** directly and the default will be creating new **Cycling Stage**.

b. Create new step: the user can create new step **Before** or **After** the currently selected step

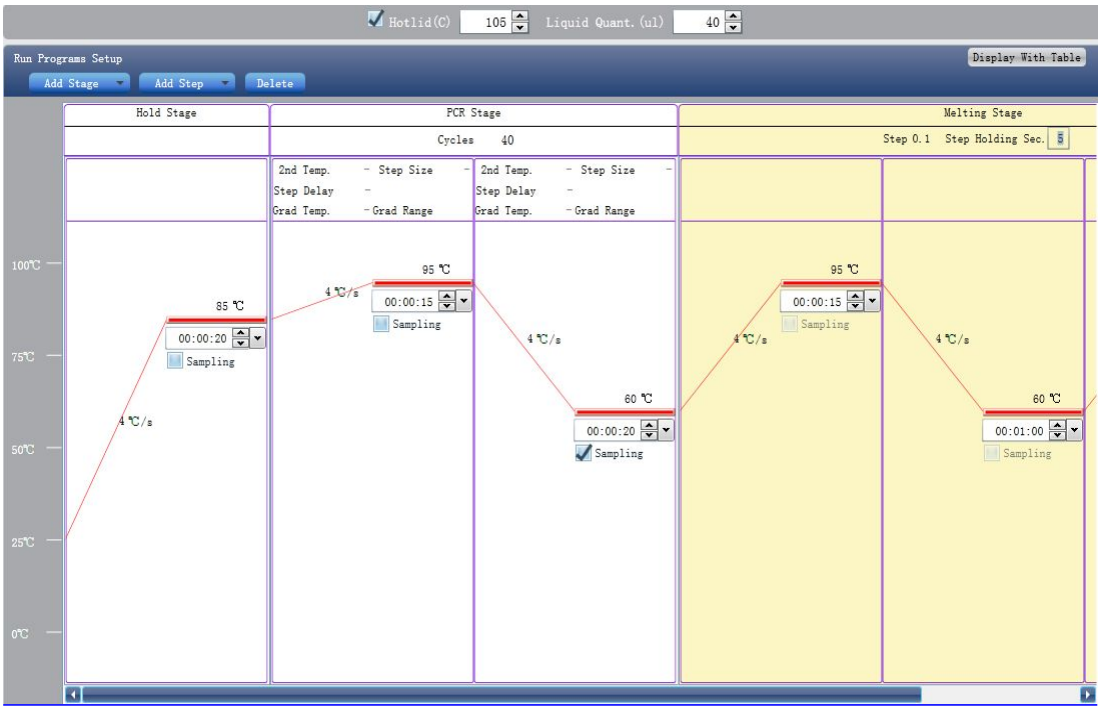
※The user can also click **Add Step** and the default will be adding new Step at the end of currently selected stage or after currently selected step.

c. Delete: the user can delete currently selected step or stage

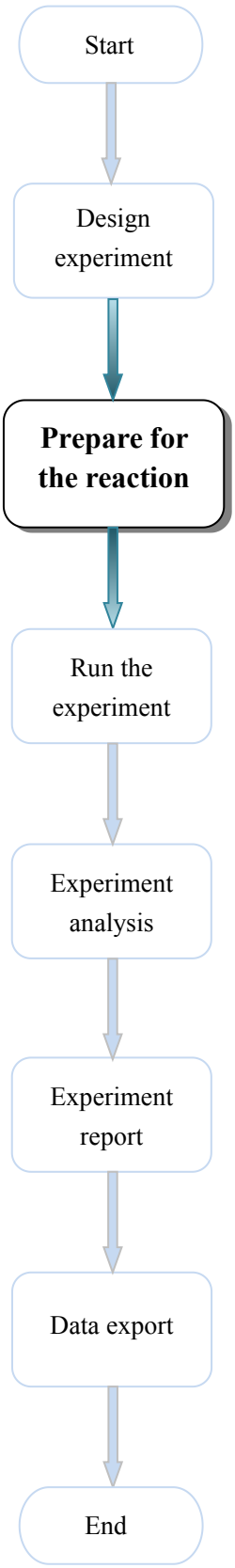
d. Display form: click **Display With Table**▶ new window will pop up▶the details of current experiment will be displayed in table

e. Set up the experimental data of the hold stage, cycling stage and melting stage melting section

f. Set up hotlid temperature and liquid quantity


Hotlid(C) 105 Liquid Quant.(ul) 40
Run Programs Setup
Add Stage
Add Step
Delete
Display With Table
Hold Stage
PCR Stage
Melting Stage
Cycles 40
Step 0.1 Step Holding Sec. 5
2nd Temp. Step Size
Step Delay
Grad Temp. Grad Range
100℃
75℃
50℃
25℃
0℃
85 ℃
00:00:20
Sampling
4 ℃/s
95 ℃
00:00:15
60 ℃
00:00:20
00:01:00

2. Prepare for Reaction



The user should make full preparations prior to the experiment:

• Ensure appropriate materials are used.

• Ensure the arrangement of PCR reaction plate is consistent with the setting layout of reaction plate in Section 1.4.

To open and modify absolute quantification detection program files

To open an absolute quantification program file

The methods to open parameter setup file of absolute quantification real-time PCR detection program include the followings:

After entering "Setup Program" interface, click " " or "File(F) →Open (O) Ctrl+O", pop up a dialog box, find out directory of the target file, select target file, then click "Open (O)" to open a setup parameter file of an edited system default directory.

Click "File (F) →Import Setup Parameters (I)" to open saving setup parameters in the system default directory (impossible to import running result).

Click "System Parameters (P) →Load Customized Parameters (P)" to open the saved user customized parameter file of file format *.ucp.

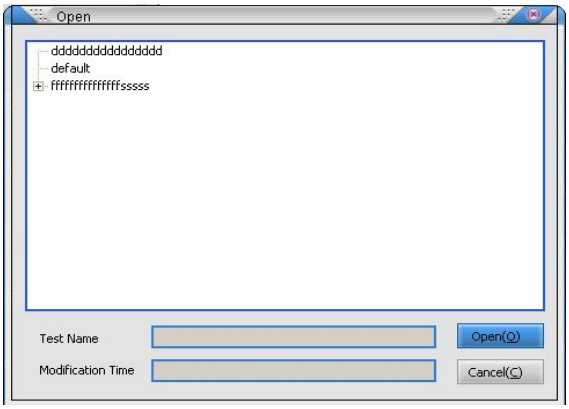
The methods to open the detection result file of absolute quantification PCR detection program include the followings:

Through "File (F) →Import(M)" open the absolute quantification detection result file of non-system default directory (detection program file format *.fqd,*.fqj).

Through "File (F) →Import SNP File (N)" open SNP detection result file of non-system default directory (detection program file format *.fqs,*.fqd).

Through "File (F) →Import Relative File (R)" open the relative quantification detection result file of non-system default directory (detection program file format *.fqx).

The opened interface simultaneously displays the test name and modification time, which will provide information of helpful note for following data analysis or opening program file.



To open a program file interface

Caution : Under opening mode, the user can input set parameters of detection program but cannot input detection result.

The file requiring analysis of the detection result may be opened only through "Import", "Import SNP File" and "Import Relative File".

To modify an absolute quantification program file

Opening a not-running detection program file may modify each setup parameter of program file.

Through opening a runned detection program file, the parameters of “Setup program” interface can’t be modified.

For saving the modified file, refer to “3. Saving of absolute quantification detection program file”.

Storage of absolute quantification detection program file

After program running the setup parameters and detection result of the absolute quantification detection program file will be automatically saved in system default directory and the detection file also may be as per actual requirements subjected to manual customized saving.

Click “” or open “File (F) →Save (S)” to save the file in default directory.

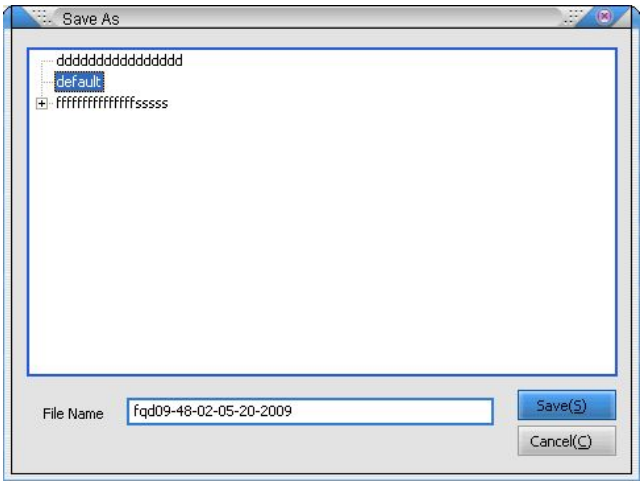
Click “File (F) →Save As (A)” to pop up file save as dialog box, under the system default directory select saving sub-directory and after determining the saving name click “Save”.

Click “File (F)” and press “Ctrl+S” to make rapid saving operation.

Click “File (F) →Export (X)” to save the detection file in non-system default directory with file format *.fqj.

Click “Saved User Customized Parameters (P)” of “System Parameters (P)” pull-down menu and save the setup parameters as user customized parameter file with file format *.ucp.

When saving detection program file, the default saving folder is user name and the default saving file is the test name. In case of no user name or test name, the default saving folder is default and the default saving file name is: fqd-hh(hour)-mm(minute)-ss(second)-mm(month)-dd (day)-yyyy(year).



Program file saved as interface

To set up detection program

Compositions of detection program

The absolute quantification real-time PCR detection program file consists of parameter-setup, running and detection result of the detection program. The entire detection system consists of Setup Programs, Sample Data, Run program, Quantitative Analysis, Melting Curve Analysis and Data Inquiry.

Setup Programs: This part mainly sets up the detection program, program section and its

parameters.

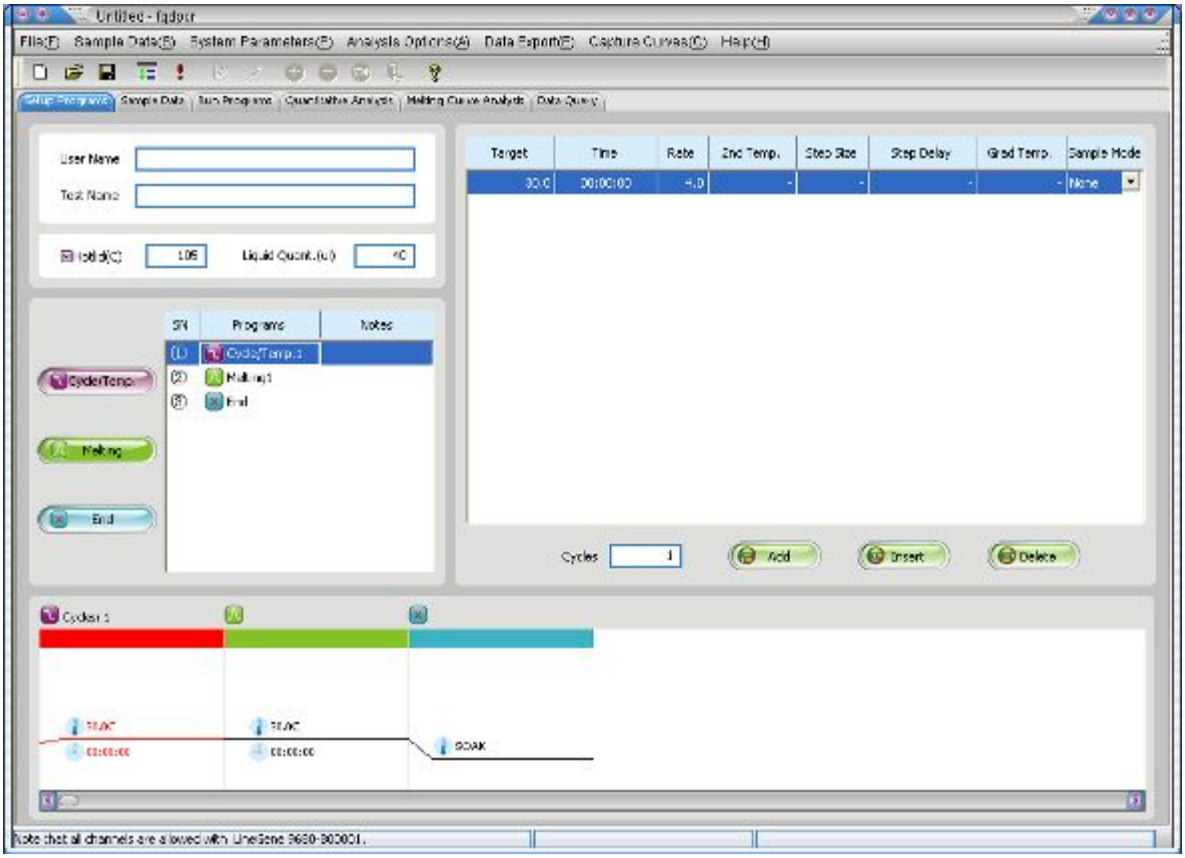
Sample Data: It sets up the sample information of detection program.

Run program: During program running process temporarily modify the setting up of the program, and real-time observe the change of each detection parameter of the detection program.

Quantitative Analysis: It makes quantitative analysis of detection result and saves and outputs the quantitative analysis result.

Melting Curve Analysis: It makes melting curve analysis of detection result and saves and outputs the melting curve analysis result.

Data Inquiry: Find out the sample information and its detection result of the corresponding sample as per the input inquiry condition.



Absolute quantification detection program setup interface

Procedures of setting-up detection program

To input user name

The user can input the user's name in the setup program interface directly.

Since at utmost 20 characters are shown in the user name column, for the input name of more than 20 characters merely the first 20 ones are displayed.

The user name does not input to the user name column and thus the edited program file is saved in the default folder.

When saving program file the user name will be automatically established as the default folder name.

To input test name

The user can input test name in the setup programs interface directly.

Since at utmost 20 characters are shown in the test name column, for the input name of more than 20 characters merely the first 20 ones are displayed.

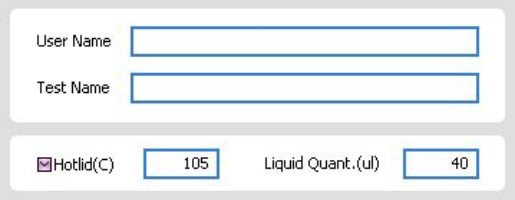
Setting-up of hot-lid

Click selection box at left of hot-lid to select opening hot-lid or not.

After selection, directly input the setting up temperature of hot-lid.

The temperature set for the hot-lid shall be at least 10°C higher than the maximum temperature during sample running to avoid reagent evaporation.

The setting up temperature range for the hot-lid is 30°C～110°C.



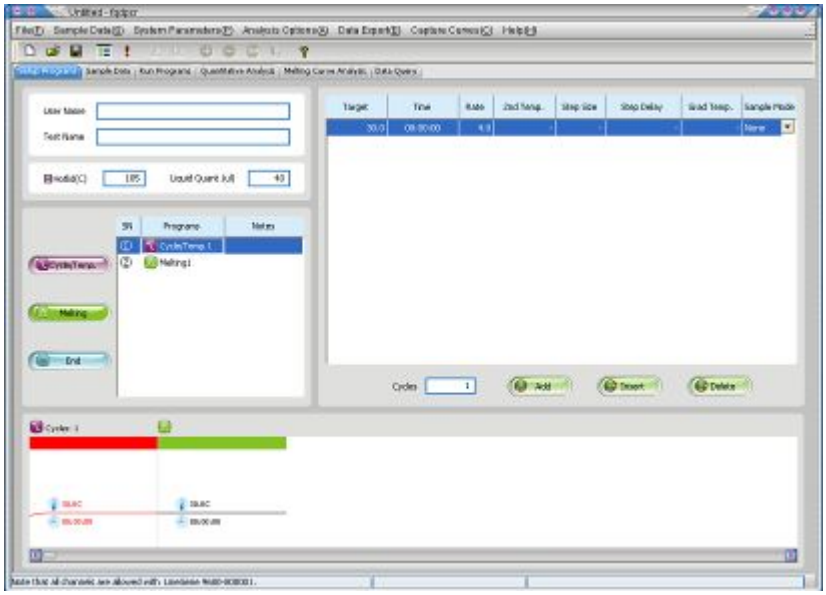
Setting-up of liquid quant

The user can input liquid volume in the setup programs interface directly.

The setting up range of liquid volume is 5μl～100μl and it may be setup as per actual conditions to optimize the system's detection control.

Setting-up of analysis mode

The analysis mode can be determined as per test detection purpose or contents: "Cycle/Temp." or "Melting". From the setting up program interface click "Cycle/Temp." or "Melting" button to select corresponding analysis mode and setup the analysis mode.



Analysis mode setup

Setting-up of cycles/constant temperature analysis mode

After clicking "Cycle/Temp." button from the setting up program interface, the program segment and program section setup column will automatically pop up the added "Cycle/Temp. 1" program and program section.

Each program segment may be edited through adding, deleting or moving in the program segment column.

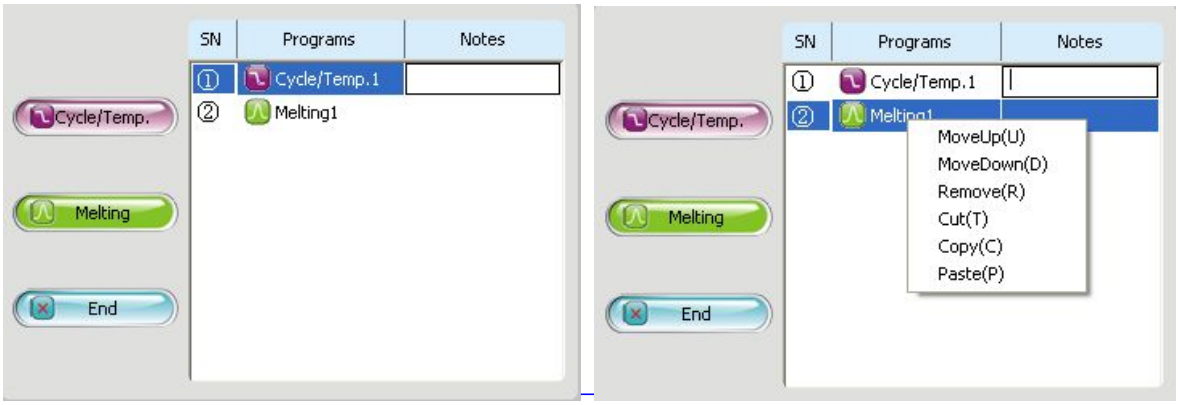
In the program section, it can be edited, such as quantity, target temperature, time, rate, 2nd temp., step size, step delay, grad temp., sample mode and cycles.

a) Adding /removing /moving main program segment

Adding: After clicking "Cycle/Temp." button, the system will automatically in the right program editing column add program 1 "Cycle/Temp. 1". Re-clicking "Cycle/Temp." will add program 2, 3…shown in left of Fig. 4-6). For remark or explanation to program, click remark column of the said program to directly input the information of 20 characters.

Removing: Select the to-delete program item, click the right key, and select "Remove" to delete the unnecessary program segment.

Moving: Select the program item that need to be moved, click the right key, and select "Moveup" or "Movedown" to adjust the position of program segment.



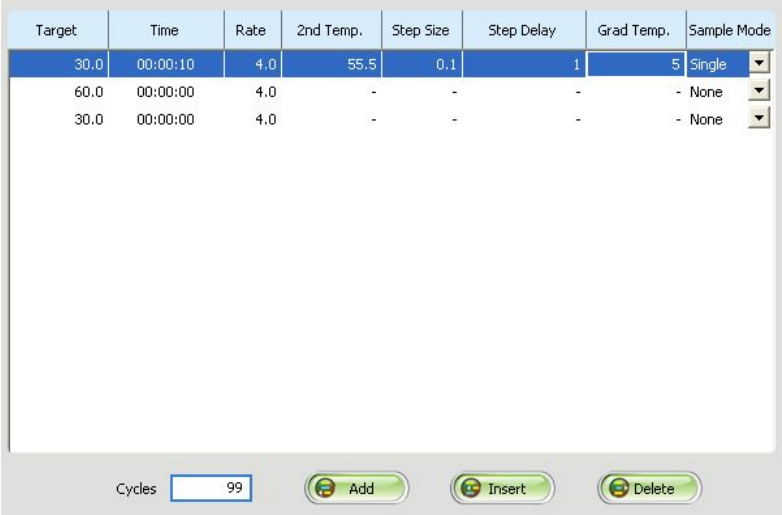
Setup interface of cycles/constant temperature main program segment

b) Adding /deleting program section

Adding: After clicking "Add" button, a newly added program section will occur following the last program section.

Deleting: Click any position of the line of the program section to select the said program section and then click "Delete".

Inserting: After selecting a program section with mouse and clicking "Insert", a newly inserted program section will occur over the said program section.



Setup interface of cycles/constant temperature program section

Note: The deleting /adding of program section may be used only with "Cycle/Temp." analysis mode.
The program section is inserted only before the current program section and in case of mistake in operation it may be re-inserted after deleting.
Each program segment may setup at utmost 20 temperature control program sections.

Caution: The parameters of newly-added program section are system's default parameters and they may be modified as per requirements.

c) Setting up cycles of detection program

The setting up of cycles is merely applicable to the program segment of analysis mode "Cycle/Temp." and in case of analysis mode "Melting" the program mode display interface will have no setup column of cycles.
The set value of cycles may be directly input.
The input value of cycles is integral from 1 to 99.

Setup of cycles

d) Setup of parameters of program section

Target temperature: It may be directly input as per actual condition with setting up range of 4～105°C.
Time: It may be directly input.
After clicking and selecting time column, pull-up and pull-down key will appear at its right side

and time may also be input through clicking pull-up and pull-down key.

The time display format of time column is *hour: minute: second.*

Rate: It may be directly input and its default value is 4.0°C/s and setting up range is 0.1°C/s～4.0°C/s.

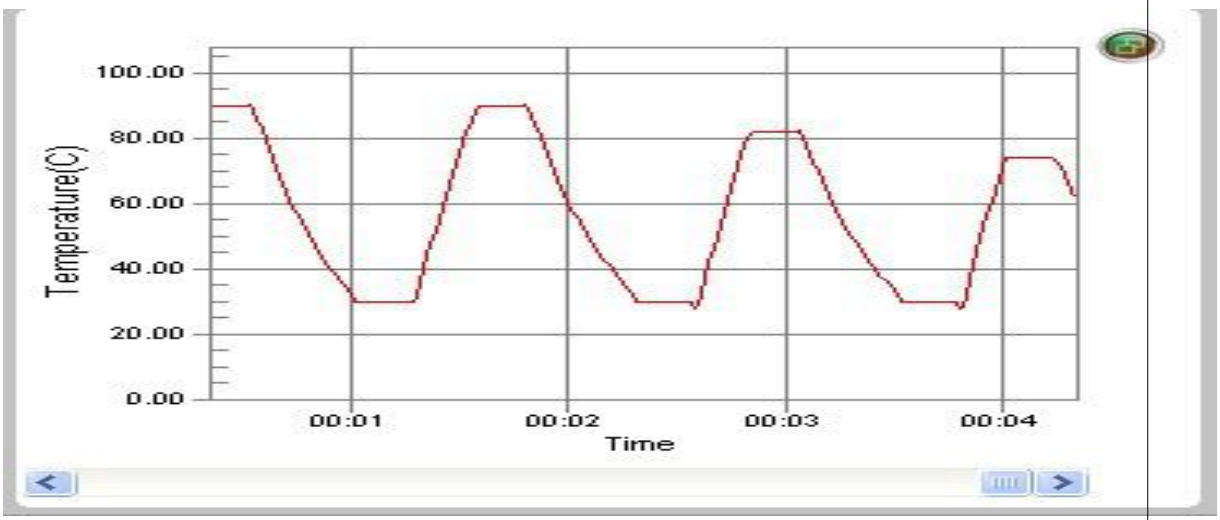
2nd Temp.: It may be directly input and its default value is "—" and setting up range is 4°C～105°C.

Step Size: It may be directly input and its default value is "—" and setting up range is 0.1°C～9.9°C.

Step Delay: It may be directly input and its default value is "—", the minimum is 1 and the maximum can't be higher than the set cycles.

Grad Temp.: It may be directly input and its default value is "—" and setting up range is 1°C～36°C.

Target	Time	Rate	2nd Temp.	Step Size	Step Delay	Grad Temp.	Sample Mode
90.0	00:00:01	4.0	74.0	8.0	2	-	None
30.0	00:00:01	4.0	-	-	-	-	Single

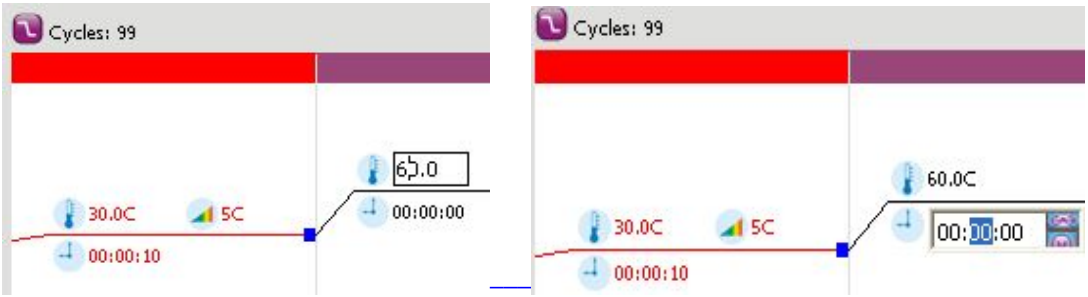


Target	Time	Rate	2nd Temp.	Step Size	Step Delay	Grad Temp.	Sample Mode
30.0	00:00:10	4.0	55.5	0.1	1	5	Single
60.0	00:00:00	4.0	-	-	-	-	None
30.0	00:00:00	4.0	-	-	-	-	None

Setup of parameters of program section

The time and target temperature of each program also may be modified in analog display area.

As shown in the below diagram, the top of curve is the target temperature and the active figures are clicked to modify the start temperature and the temperature value may be directly input. The bottom of the curve is time and the active figures are clicked to pop up up/down key and to modify time.



Modification of each program time and temperature of analog display area

e) Setup of sample mode

Merely a temperature control program section is selected for sampling through the side pull-down box. If the temperature control program section is selected as "Single" sampling, after completion of running of this section, the system will scan and collect fluorescence data of the reagent sample.

Setup of melting curve analysis mode

Setting up of melting curve analysis mode and "Cycle/Temp." are basically same merely with different parameter contents of program section. In the program section, the user can edit the target temperature, start temperature, time, step temperature and sample mode.

a) Setup of parameters of program section

Target: It may be directly input as per actual condition with setting up range 4～105°C.

Start temperature: It may be directly input as per actual condition with setting up range 4～105°C.

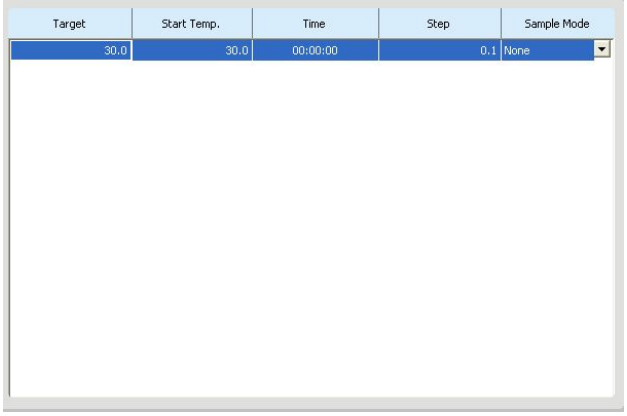
Time: It may be directly input.

After clicking and selecting time column, pull-up and pull-down key will appear at its right side and time may also be input through clicking pull-up and pull-down key.

The time display format of time column is *hour: minute: second.*

Step: It may be directly input and its default value is "—" and setting up range is 0.1°C～9.9°C.

Caution: The step temperature denotes the each ascending or descending temperature value.



Setup interface of melting curve program section

b) Setup of sample mode

"None" or "Step" is selected through the pull-down box of sample mode column. If "None" is selected, during the detection program running process no sampling shall be made. If "Step" is selected, during the detection program running process for each increase of a step temperature one sampling shall be made.

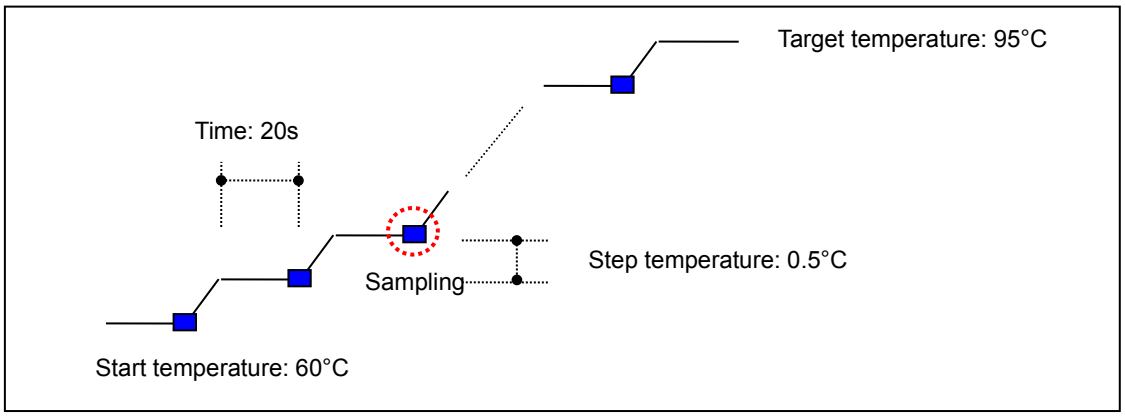


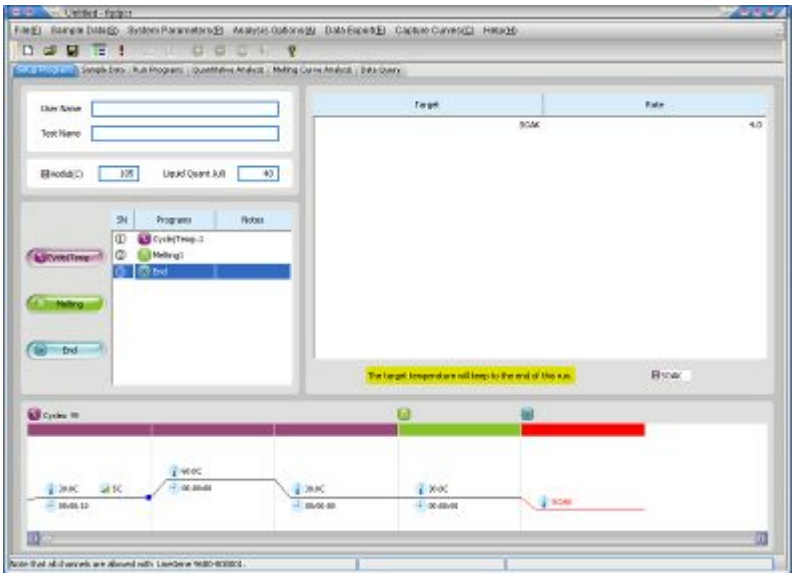
Illustration of setup of melting curve

Setting-up of end-running mode

After clicking "End" button from the setting up program interface, the program segment and program section setup column will automatically pop up the added " End" program and program section.

In the running program segment setup column, " End" program is merely located at the last of each program segment and it may be deleted.

In the program section, its target temperature and rate may be edited.



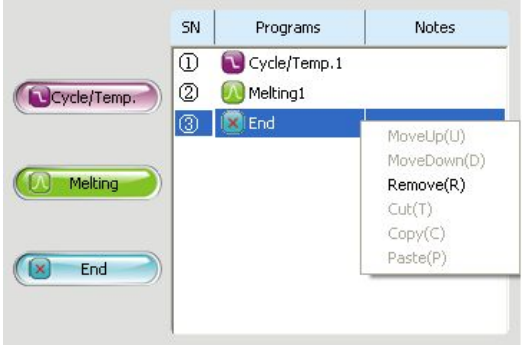
Setup interface of end-running mode

a) Adding /removing /moving main program segment

Adding: After clicking " End" button, the system will automatically in the right program editing column add termination routine " End" and the termination routine is merely allowed to add once. For remark or explanation to program, click remark column of the said program to directly input the information of 20 characters.

Removing: Select the "Remove" program item, and click the right key.

Moving: " End" is unable to execute the moving command and the said program segment is merely located at the last of each program segment.



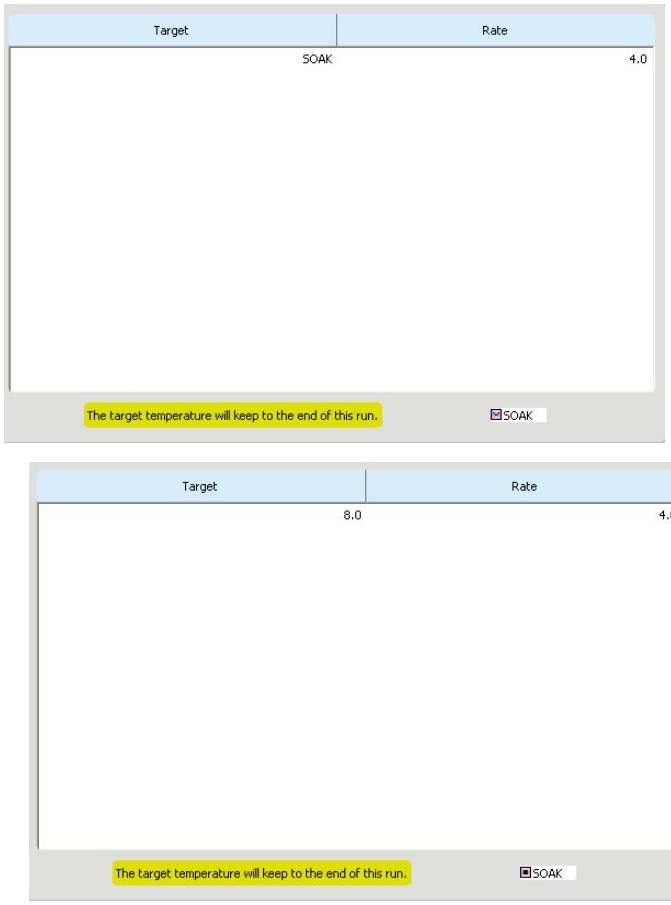
Setup interface of main program segment

b) Setup of parameters of program section

Target: For “SOAK” mode, the system default target temperature is 8°C.

For non “SOAK” mode, the target temperature may be directly input with setting up range 8～105°C.

Rate: It may be directly input as per actual condition with setting up range 0.1～4°C/s.

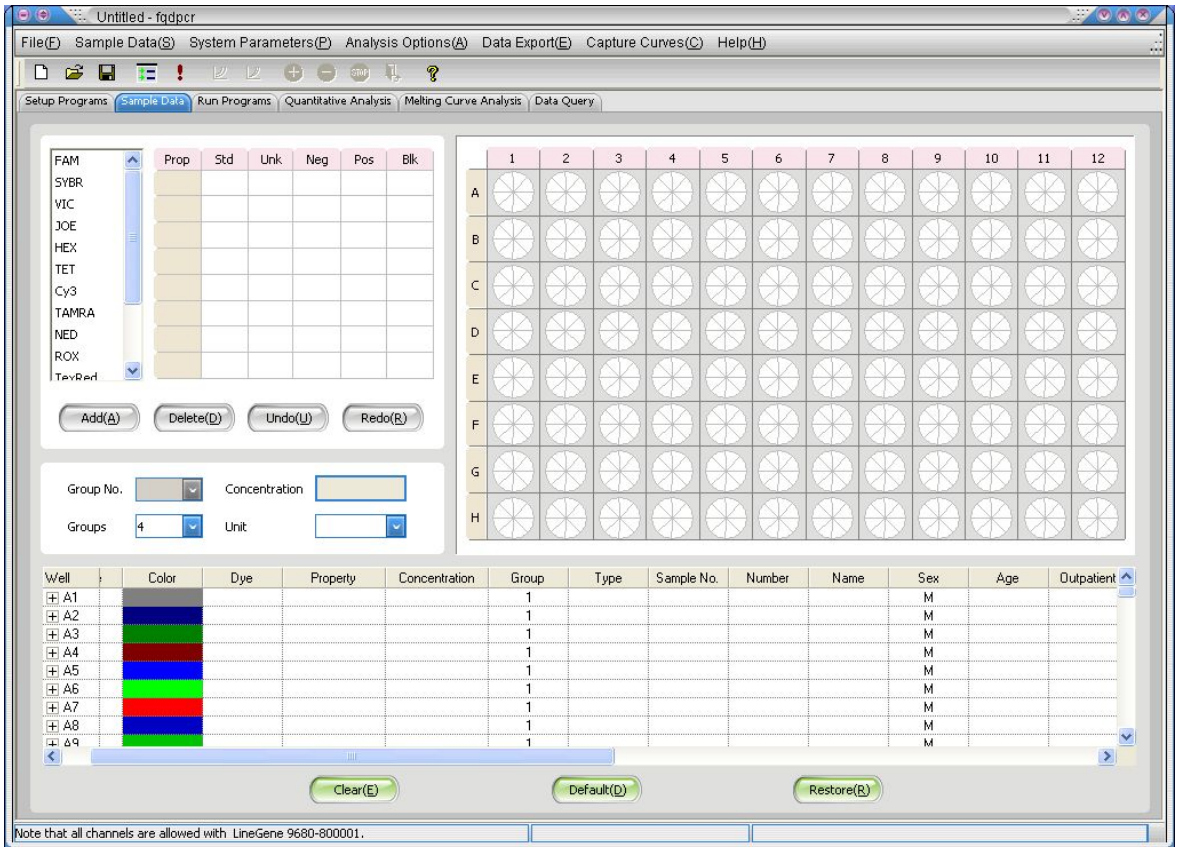


Setup interface of program section

Caution: If “SOAK” mode is selected in termination routine segment, at end of program running it will execute the below 10°C low-temperature storage command.

Input of sample information

Click “Sample Data” to enter sample information setup interface and set up the input, saving and modification of sample information.


Untitled - fqdpcr
File(F) Sample Data(S) System Parameters(P) Analysis Options(A) Data Export(E) Capture Curves(C) Help(H)
Setup Programs Sample Data Run Programs Quantitative Analysis Melting Curve Analysis Data Query
FAM SYBR VIC JOE HEX TET Cy3 TAMRA NED ROX TexRed
Prop Std Unk Neg Pos Blk
Add(A) Delete(D) Undo(U) Redo(R)
Group No. Concentration
Groups 4 Unit
1 2 3 4 5 6 7 8 9 10 11 12
A B C D E F G H
Well Color Dye Property Concentration Group Type Sample No. Number Name Sex Age Outpatient
A1 A2 A3 A4 A5 A6 A7 A8
Clear(E) Default(D) Restore(R)
Note that all channels are allowed with LineGene 9680-800001.

Setup interface of sample information

Setting-up of detection test tube display area

In the detection test tube display area, the detection test tube may be selected and the sample information of the selected test tube may be edited through the following modes:

Clicking "" of test tube display area to select single test tube.

Through pressing Ctrl key several test tubes may be irregularly selected.

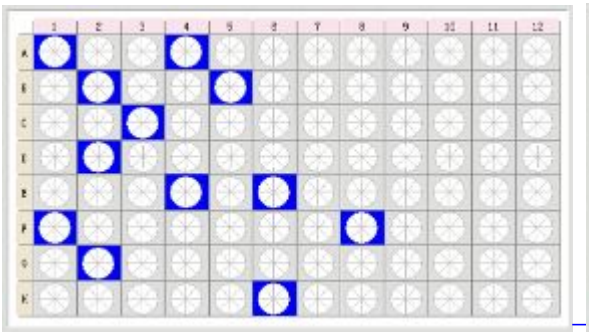
Through pressing Shift key several test tubes may be regularly selected, i.e. the selected test tubes are arranged in a rectangular. If pressing on Shift key and selecting "A1" and then "F9", all test tubes in the rectangular area with "A1" and "F9" as diagonal will be selected

Through pressing on and moving mouse left key, several test tubes may be regularly selected.

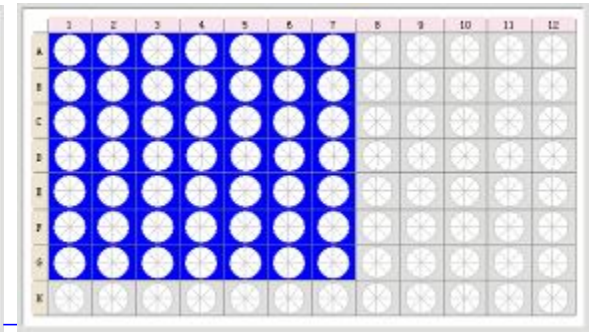
Clicking line number "A, B, C…" of the table, the entire line of test tubes may be selected.

Clicking row number "1, 2, 3…"of the table, the entire row of test tubes may be selected.

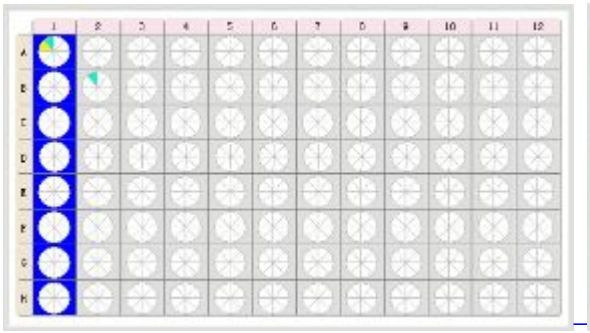
After selection of detection test tube, the sample information of the selected detection test tube (except for sample color) may be integrally input and modified. For example, if "A1" and "B2" are selected and "A1" sample name is changed as "Sample 1" and "B2" sample name will be correspondingly changed as "Sample 1".



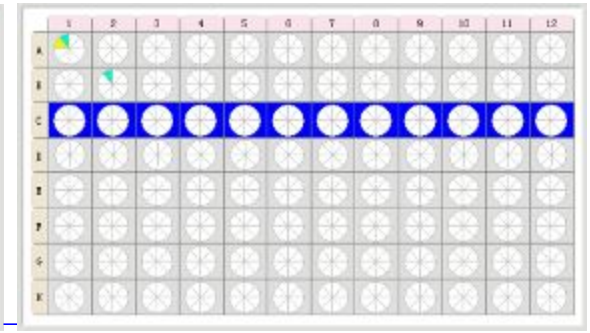
Irregular selection of test tube



Regular selection of test tube



Selection of entire-row test tubes



Selection of entire-line test tubes

Selection of test tube display

Group setup

In the group setup area, click the pull-down arrow at right of group number and from the pull-down box select the group numbers of sample: 1,2,3,4 and click pull-down arrow at right of the groups to setup the group of the selected sample.

Group and concentration setup interface

Input of concentration

In the concentration setup area, click pull-down key at concentration unit right and from the pull-down box select dye concentration unit: copies/ml, IU/ml, fg/ml and pg/ml. In the concentration setup area current dye concentration of the selected sample may be directly input.

Dye addition

The dye may be added as follows:

In dye addition selection area, after clicking dye and then "Add (A)" button, the dye will be automatically identified to the detection test tube and the right side dye attribute column and the detection test tube display area will also display corresponding color.

Click "Delete (D)" button to cancel corresponding dye setup.

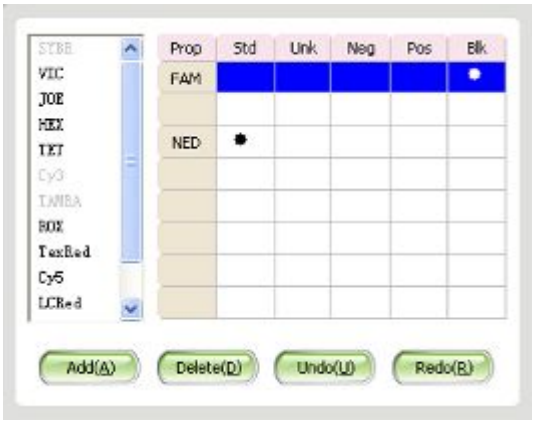
Click "Undo (U)" button to cancel the latest operation.

Click “Redo (R)” button to cancel the undo operation.

In the dye attribute setup area; click the corresponding position of table to select the sample attribute.

At selection of dye, when a dye is selected, partial dyes display grey, which denotes that these dyes are in a same channel and they are unnecessary to re-select.

The sample will have the following attributes: standard, unknown, negative, positive and blank.

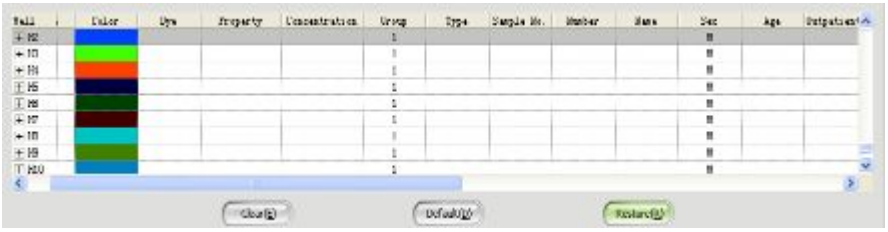


Setup of dye addition and attribute

Editing of sample information

In the sample information area, the sample materials information has totally 22 default items, of which the group, concentration, dye and attribute shall be setup in corresponding setup column and the others may be selected and input as per actual requirements.

The position of sample column in the list may be modified through mouse drag.



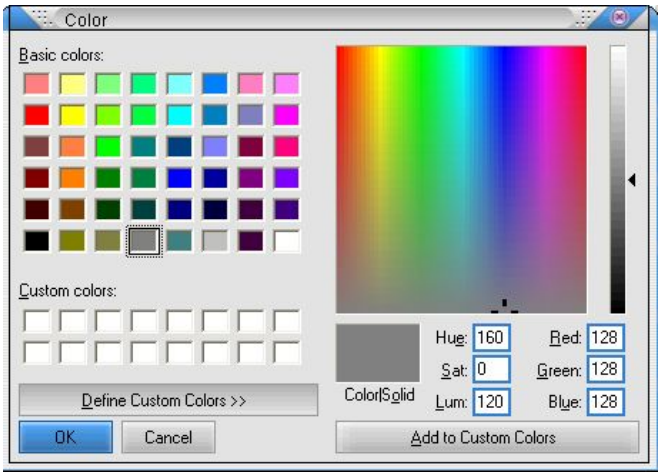
Sample information input interface

The sample materials are input as follows:

Well: Click “+” to develop the tabulation and list contents of 8 lines “F1～F8” and show the dye information of 8 detection channels corresponding to the said well sample.

Sample: After clicking a column, the contents may be directly input. The said column can’t be complete blank; otherwise the program will be impossible to automatically run. The default sample name is well number, e.g. “H12”.

Color: Double clicking a column will pop up a color dialog box. After selection of a new sample color in the color dialog box, clicking “Enter” will replace the sample default color.



Color dialog box

Type: The contents may be directly input.

Sample No.: The contents may be directly input.

Number: The contents may be directly input.

Name: The contents may be directly input.

Sex: Click and select a column, double click it to pop up the pull-down key at its right, click the pull-down key and from the pull-down box select male, female and unknown.

Age: The contents may be directly input.

Outpatient No.: The contents may be directly input.

Inpatient No.: The contents may be directly input.

Bed No.: The contents may be directly input.

Case No.: The contents may be directly input.

Doctor: The contents may be directly input.

Dept.: The contents may be directly input.

Submitting date: Click and select a column, double click it to pop up the pull-down key at its right, click pull-down key, pop up calendar, move the mouse to the selected date on the calendar and click the said date to input detection date.

Diagnosis: The contents may be directly input.

Sampling time: Click and select a column, double click it to pop up the pull-down key at its right, click pull-down key, pop up calendar, move the mouse to the selected date on the calendar and click the said date to input sampling time.

Status: The contents may be directly input.

Nationality: The contents may be directly input.

Notes: The contents may be directly input.

There are 3 shortcut keys below the sample information list: Clear (E), default (D) and restore (R).

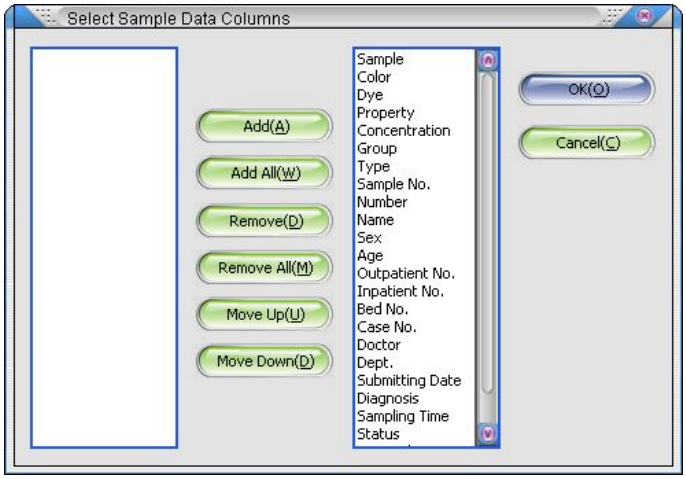
Clear (E): Clicking the said key will eliminate all sample materials.

Default (D): Clicking the said key will automatically show the setup of system default sample materials.

Restore (R): Clicking the said key will restore the sample materials to its original state.

Selection of sample data column

If the setup of system sample data column is deemed unsuitable, the sample data column may be selected. Click "Sample Data (S)" in menu column, from the pull-down menu select "Select Sample Data Column (E)", pop up sample data columns and select dialog box.



Dialog box of sample data columns selection

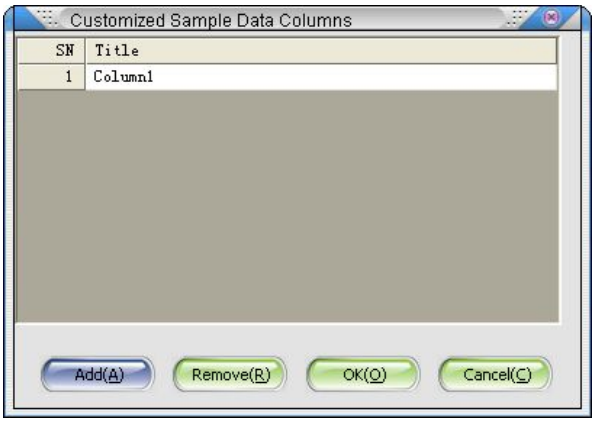
Click "Add (A)"or "Remove (D)" to select desired column, which will be displayed in the right box.

Select a sample column in the right box and click "Move up (U)"or "Move down (D)" to change the position of the said column in sample information list.

Click "Add All (W)" or "Remove All (M)" to make integral adding or deleting operation.

Customized sample data columns

Customized sample data columns may be added if necessary. From the pull-down menu of "Sample Data(S)" select "Customized Sample Data Column … (C)" and pop up dialog box of customized sample data columns.



Dialog box of customized sample data column

Click "Add (A)" button to automatically add one line. Click column 1 to make edition and input the name of customized sample data column.

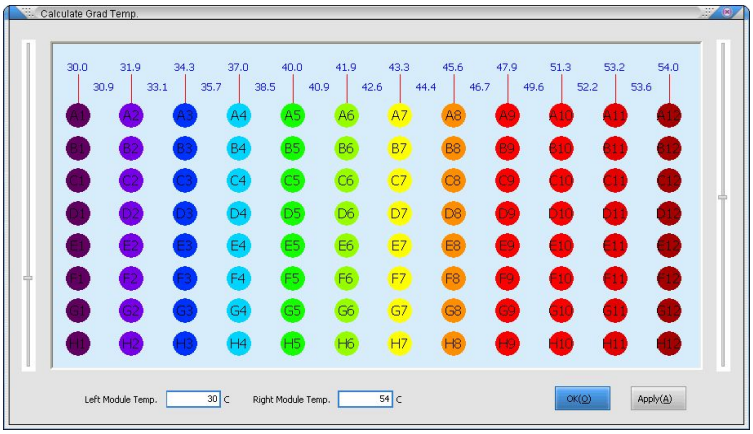
After clicking "OK (O)" button, the customized sample data column will appear in the column at left of dialog box of the sample information selection column.

Clicking "Remove(R)" button will delete the customized information column.

Clicking "Cancel (C)" button will close the dialog box.

Calculation of grad temp.

At setup of gradient parameter, the temperature of each sample well at each set gradient state may be referred to grad temp. calculation diagram. The sample is divided into 12 rows and each row has the same grad temp.. Clicking the “Grad Temp. Calculation (C)…” of the “System Parameters (P)” pull-down menu will pop up a calculation grad temp. dialog box.



Grad temp. calculation diagram

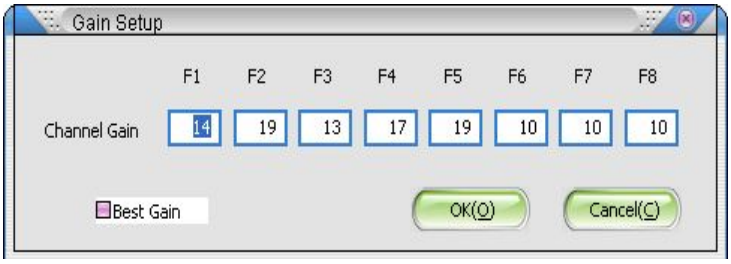
Gain setup

The LineGene 9600 series Fluorescent Quantitative PCR Detection System has totally 8 detection channels F1, F2, F3, F4, F5, F6, F7 and F8, each channel’s gain can be adjusted independently.

Gain is the amplification factor of fluorescence intensity signal and adjustment of gain value will change the magnitude of fluorescence intensity output signal, scope of adjustment is from 0 to 20. The system provides default gain value to greatly shorten the time to determine the gain value through test and thus greatly enhance instrument suitability. Man-made setup may be made as follows:

Clicking “System Parameters (P) →Gain Setup (G)…” menu enter “Gain Setup”.

Directly input gain value and click “OK”.



Setup gain

Function of best gain

Because gain set by user is improper, scanned fluorescence value may probably too large or too small. If fluorescence value is too high, electrical signal will saturate, which causes display of interface corresponds with actural amplification. If fluorescence value is too small,

it is not easy to observe. The software takes amplified reagent as sample. Instrument adjust again value automatically during scanning, so that object value fluorescence gets best effect. (Fluorescence value of aplification apporaches 9000)After measurement, the gain value gotten from scan is the best gain value. User may invoke best gain at any time.

Best gain of every instrument has been measured by using usual reagent at ex-factory. When user's reagent is different from dye name of channel list or the reagent is especial, user should measure best gain.

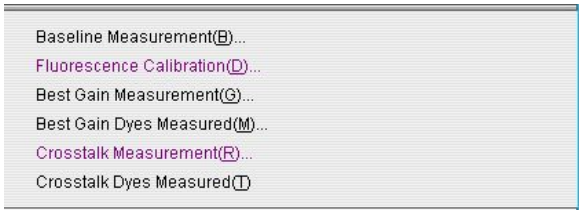
The following is calibration procedure:

User may select reagent,which is single character and pure dye, of one or more channel to measure at the same time, and put reagent in appointed wells.

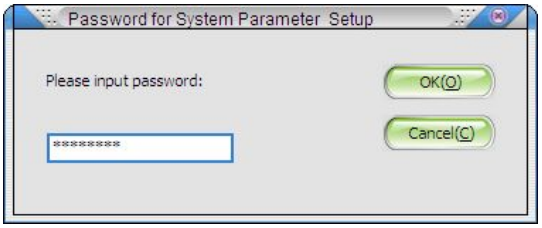
Channel	Reference well of best gain reagent
F1	A1
F2	A1
F3	A2
F4	A3
F5	A4
F6	A5
F7	A6
F8	A7

Caution: Because F1 and F2 are in the same well, dyes of F1,F2 must measured respectively.

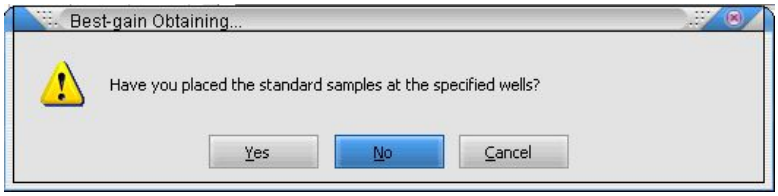
b)In the interface of sample data, to select dye, then select the "Best Gain Measurement" of the "System Parameters" pull-down menu.



c)To input password "bioerpcr" in the following window.



d)To click "Yes" in the following window, system measures best gain.



e) After running, file "Gain******.coe" is saved in installation folder, thereinto instrument number is correspondence with *. User can see dye in "Best Gain Dyes Measured(M)…" of "System Parameters (P)" pull-down menu.

f) Clicking "System Parameters (P) →Gain Setup (G)…" menu enter "Gain Setup".

g) To select "Best Gain" from "Gain Setup" interface, then click button "run" after setting parameters. During detection program running, best gain value of dye of each channel will be imported. If best gain value of some dye is not acquired, pop the prompt dialog box as follows:

Caution: When amplification, best again or less than best gain is adopted.

Addition of customized dye

If the detection-required fluorescence dye is not in the system default fluorescence dye, corresponding fluorescence dye may be added in the system through "Add Customized Dyes".

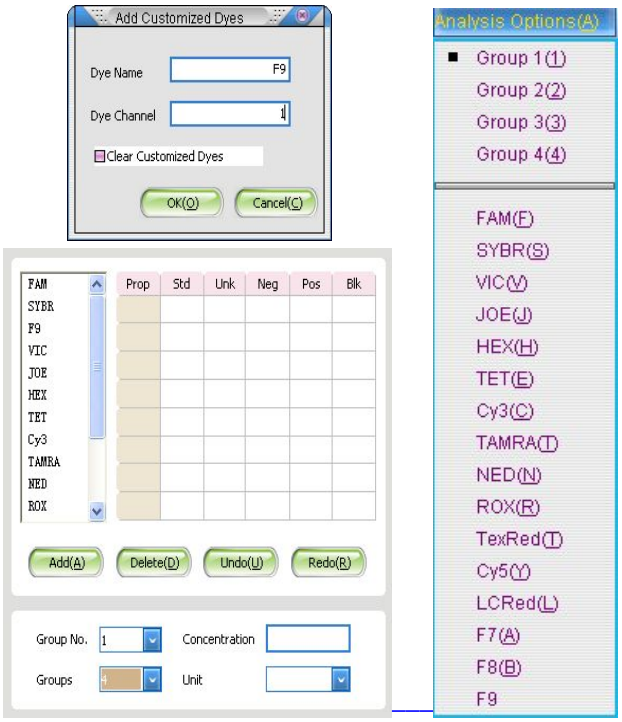
Click the "Add Customized Dyes (Y)…" of "System Parameters (P)" pull-down menu to pop up "Add Customized Dyes" dialog box.

Directly input the new-added dye name to the "Dye Name" column

Directly input the new-added dye detection channel to "Dye Channel".

Click "OK" to save the new-added dye to the pull-down menu of "Analysis Options".

Select "Clear Customized Dyes" and click "OK" to delete all customized dyes from pull-down menu of "Analysis Options".



Addition of customized dyes (e.g. F9)

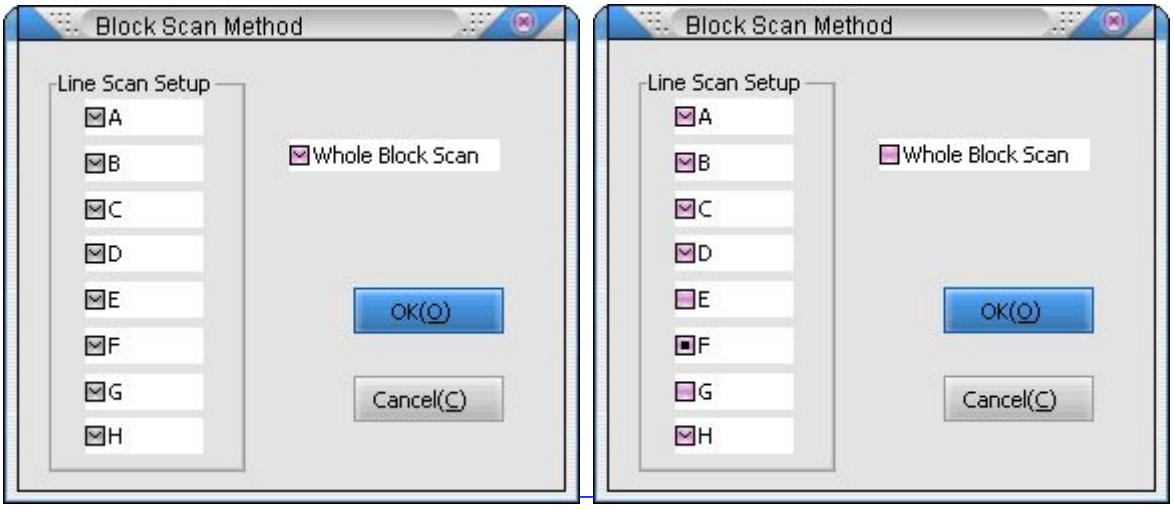
Module scanning mode

In LineGene 9600 detection process, there are 2 fluorescence scanning modes (entire scanning and in-line scanning), which may be setup through “Block Scan Method”

Click “Select Block Scan Method (M)…” of “System Parameters (P)” pull-down menu to pop up “Block Scan Method” dialog box.

After clicking and selecting “Whole Block Scan” and clicking “OK”, the instrument will conduct entire scanning during running.

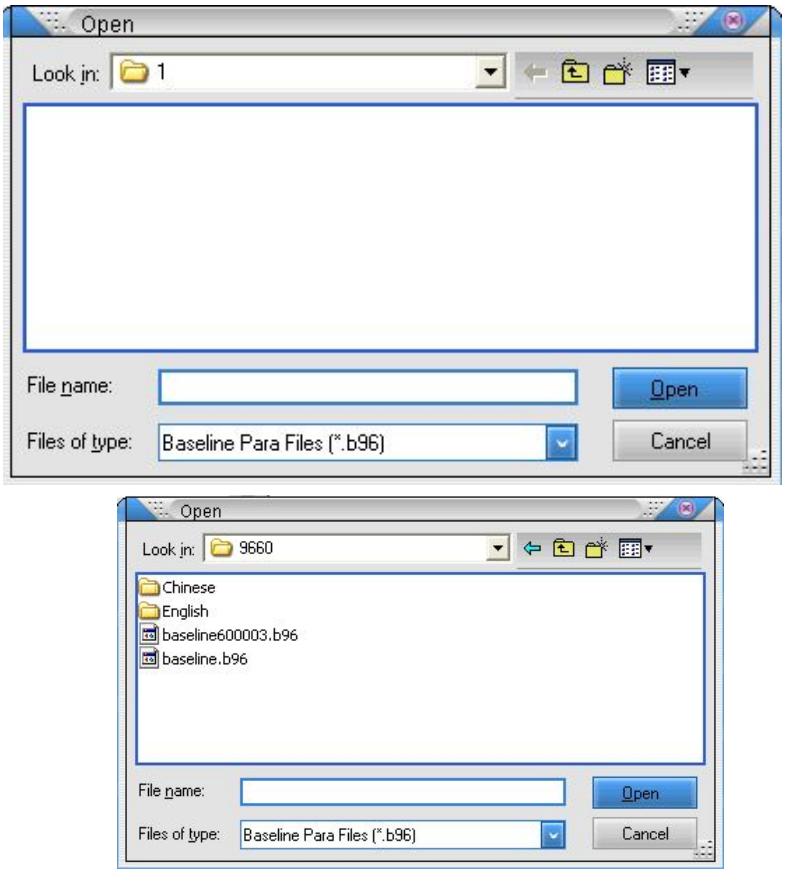
Re-clicking “Whole Block Scan” will cancel the selected “Whole Block Scan” and activate “Line Scan Setup”. “Line Scan Setup” box has 8 options (A, B, C, D, H) and through clicking 8 options, the in-line scanning may be selected and setup. After clicking “OK”, during running the instrument will make in-line scanning as per the setup.



Setup of select block scan method

To copy baseline parameters to install directory

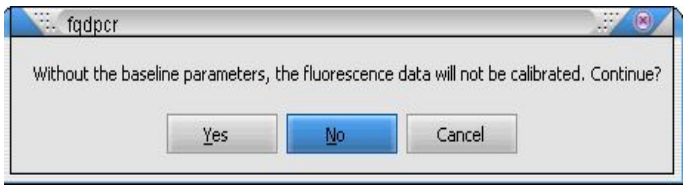
Click “Copy Baseline Parameters to Install Directory (L)…” of “System Parameters (P)” pull-down menu to pop up “Open” dialog box. You may open baseline parameters file, format of file: Baseline******.b96, thereinto instrument number is correspondence with *.



Copy Baseline Parameters to Install Directory

Baseline parameters file “Baseline******.b96” has saved in disc at ex-factory.

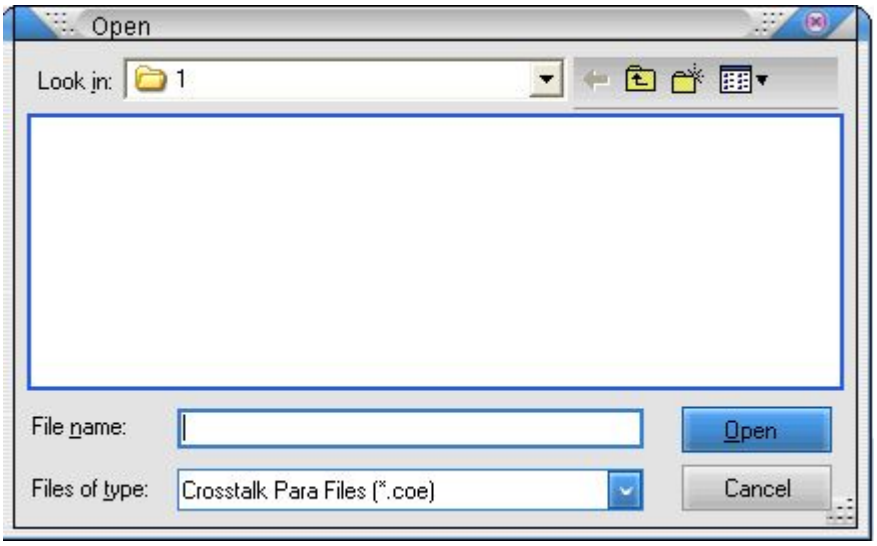
If instrument serial number does not match baseline parameters under instrument install directory, it will pop up dialog box, click “Yes”, copy parameters according to prompt, run program after quitting. If instrument serial number matches baseline parameters, system does not prompt when running.

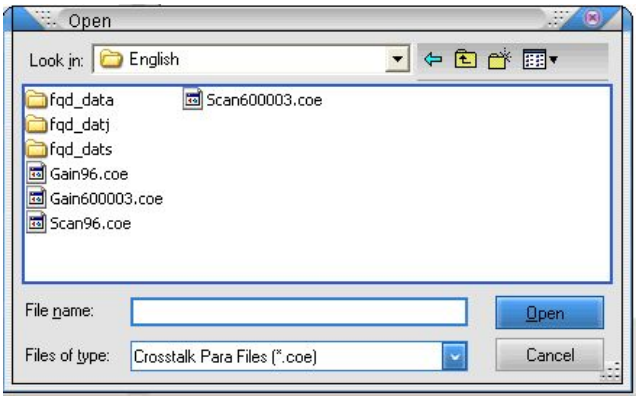


Dialog Box of Prompt

To copy crosstalk parameters to install directory

Click “Copy crosstalk Parameters to Install Directory (S)…” of “System Parameters (P)” pull-down menu to pop up “Open” dialog box. You may open crosstalk parameters file, format of file: Scan******.coe, thereinto instrument number is correspondence with *.





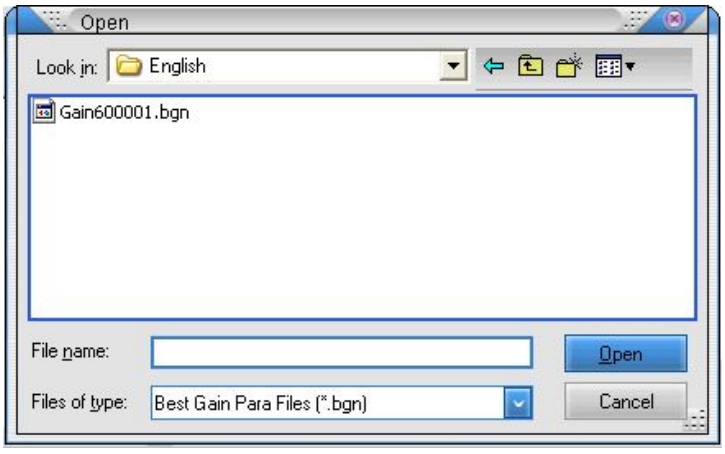
Copy Crosstalk Parameters to Install Directory

Crosstalk parameters file has saved in disc at ex-factory, File that is made by user's calibration may be selected under install directory or directory that user appoints.

After success of copy, you must quit program, then open it.

To copy best gain parameters to install directory

Click "Copy Best Gain Parameters to Install Directory (B)…" of "System Parameters (P)" pull-down menu to pop up "Open" dialog box. You may open best gain parameters file, format of file: Gain******.bgn, thereinto instrument number is correspondence with *.

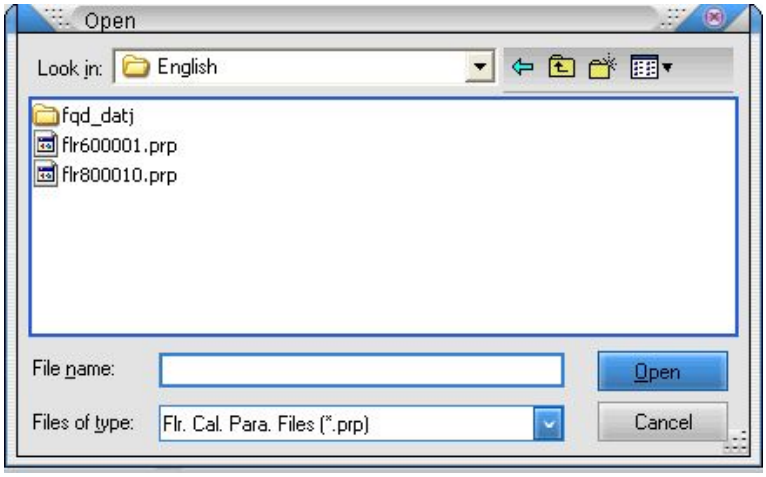


Best gain parameters file has saved in disc at ex-factory, File that is made by user's calibration may be selected under install directory or directory that user appoints.

After success of copy, you must quit program, then open it.

To copy fluorescence calibration parameters to install directory

Click "Copy Fluorescence Calibration Parameters to Install Directory (B)…" of "System Parameters (P)" pull-down menu to pop up "Open" dialog box. You may open fluorescence calibration parameters file, format of file: flr******.prp, thereinto instrument number is correspondence with *.



Fluorescence calibration parameters file has saved in disc at ex-factory, File that is made by user's calibration may be selected under install directory or directory that user appoints.

After success of copy, you must quit program, then open it.

Caution: *User can measure crosstalk dyes after fluorescence calibration.*

System prompt and alarm

The system prompt includes curve prompt function and buzzer alarm function. From the "Options for System Alarm and Tips" dialog box, the system prompt and alarm may be setup.

After starting "Tips for Curves", when the mouse point moves to curve, which is overstriking ,information prompt box of the curve will appear and the said information box will display related information of the mouse located curve (detection sample well, X coordinate, Y coordinate, selected dye, and groups of detection sample).

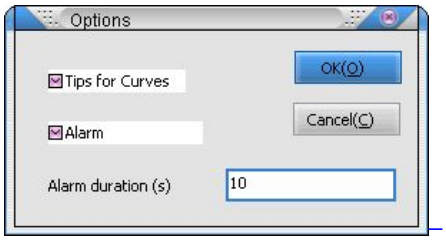
After starting "alarm", in case of instrument troubles or end of run, the instrument will send buzzing sound.

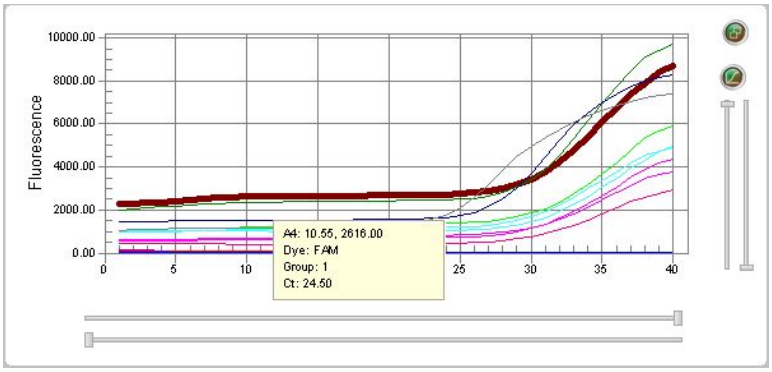
Click "Options for System Alarm and Tips (O)…" of "System Parameters (P)" pull-down menu to pop up "Options" dialog box.

After clicking "Tips for Curves", when "" of the current page changes to "" it will denote that the said function is selected.

After clicking "alarm", when "" of the current page changes to "" it will denote that the said function is selected.

Directly input buzzer alarm duration into “Alarm Duration (s)” column.
Click “OK” to save the system prompt setup.

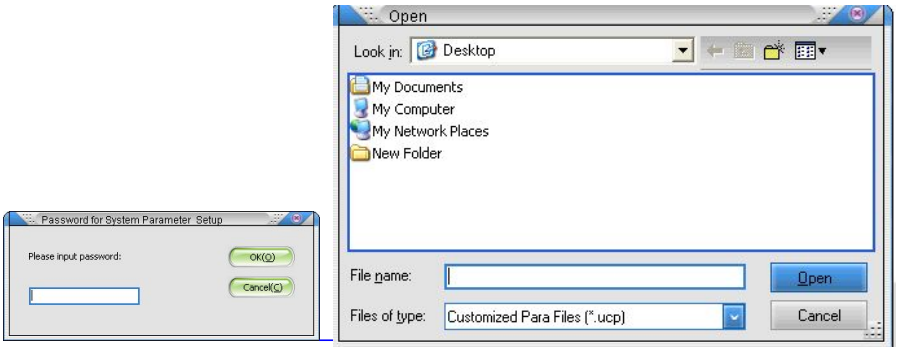




Setup and display of curve prompt function

Load customized parameters

At detection of repeated items, in order to decrease repeated input the saved customized parameters may be called through “Load Customized Parameters”.
Click “Load Customized Parameters (P)…” of “System Parameters (P)” pull-down menu to pop up “Password for System Parameter Setup” dialog box.
Input system password and click “OK” to pop up “Open“ File dialog box.
Select the desired file and click “Open” to open the saved parameters.
User customized parameter file format: *.ucp



To open user customized parameter file

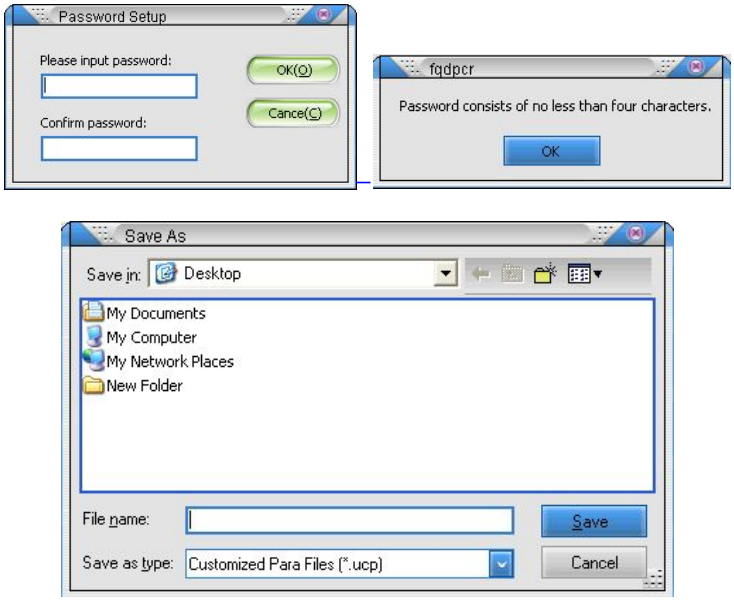
Saved as user customized parameters

Through the “Save Customized Parameters” the seted detection program parameters may be saved for call in next detection.
Click the “Save Customized Parameters (P)…” of “System Parameters (P)” pull-down menu to pop up “Password Setup” dialog box.

Input and confirm password (Caution: password over 3-digit) and click “OK” to pop up “Save As” dialog box.

From “File Name” column directly input file name and click “Save” to save the customized parameter file.

File saving type: customized parameter files (*.ucp).



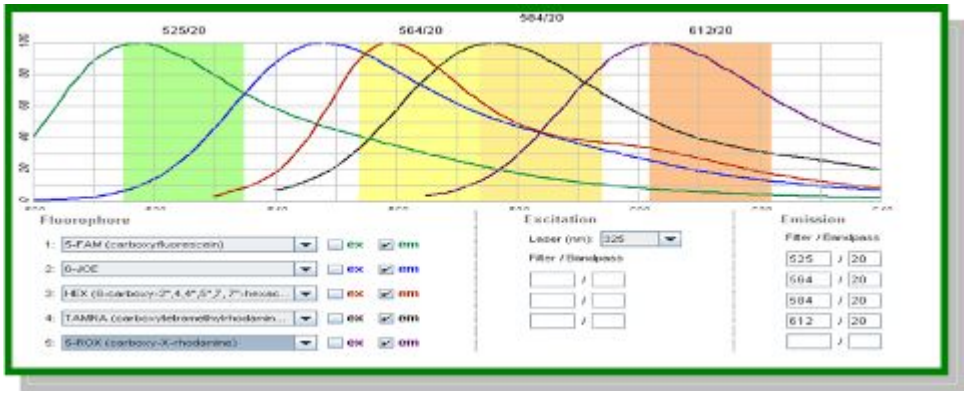
To save user customized parameter file

Crosstalk measurement

Any dye has a wide light spectrum. Filter of adjacent wavelength of F1-F8 is effective, and it is normal physics for them to overlap.

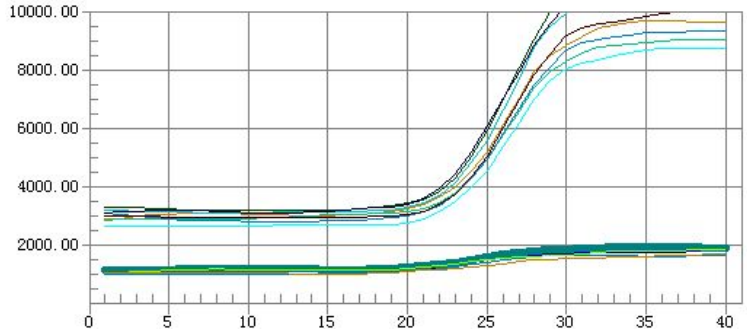
Usually, this software can correct the fluorescence among channels. It records every channel to deduct this impact later, minimize the “interference” among channels and avoid wrong judgment in same-tube multi-color synchronous detection.

In order to eliminate effect which occurs between one channel dye and the others,so that user can get multicolor detection results, the software adds function of crosstalk measurement

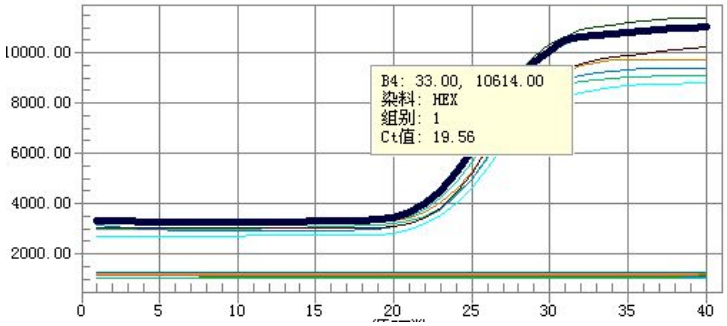


Crosstalk effect

F1’s impact on F2:



After calibration, the impact disappears:



Crosstalk of every instrument has been measured by using usual reagent at ex-factory. User may measure gain reagent. If there is no reagent in list of dye, user should name dye at suitable channel, then measure crosstalk. The following is calibration procedure:

a) User may select reagent,which is single character and pure dye, of one or more channel to measure at the same time, and put them in appointed wells.

Channel	Reference well of crosstalk reagent
F1	A2
F2	B2
F3	C2
F4	D2
F5	E2
F6	F2
F7	G2
F8	H2
Pure water	A3

3. Run the Experiment

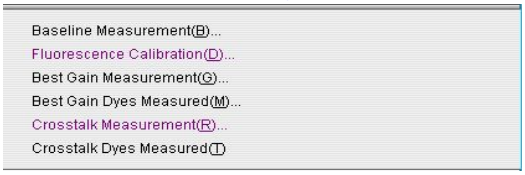
This section describes how to run operate the experiment after loading the reaction plate and covers the operating of florescence curve, the operating of temperature curve and prog

Start
Design experiment
Prepare for the reaction
Run the experiment
Experiment analysis
Experiment report
Data export
End

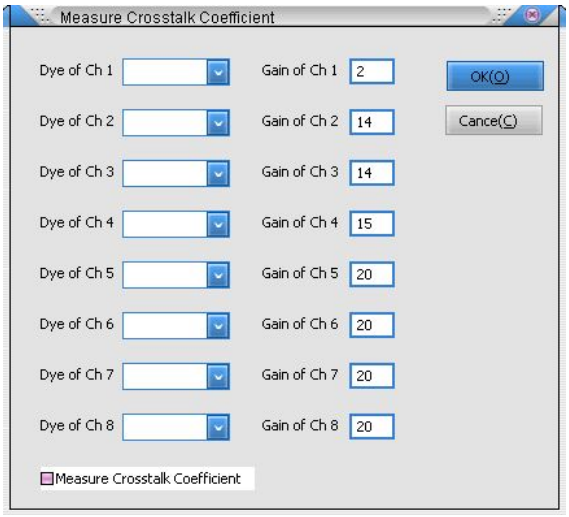
Caution: Before start, make checks and correctly start the system. Before running of program, the module shall be smoothly pushed to send locking sound and the alarm lamp is not on. The green lamp of run switch shall light on and the system shall be at running state.

Caution: If the module is pulled out or is improperly pushed, the software will show prompt and the alarm lamp will light on. At this case, temperature program can run but the fluorescence scanning data would become invalid.

b)To run a program whose sample mode is none, and the reagent volume is 40μl. During running, to select “Crosstalk Measurement ” of “System Parameters” pull-down menu.



c) To input dye and suitable gain for channel in the following dialog box, and select “Measure Crosstalk Coefficient”, then click “ok”, crosstalk coefficient is measured.


Measure Crosstalk Coefficient
Dye of Ch 1
Gain of Ch 1 2
OK(O)
Dye of Ch 2
Gain of Ch 2 14
Cance(C)
Dye of Ch 3
Gain of Ch 3 14
Dye of Ch 4
Gain of Ch 4 15
Dye of Ch 5
Gain of Ch 5 20
Dye of Ch 6
Gain of Ch 6 20
Dye of Ch 7
Gain of Ch 7 20
Dye of Ch 8
Gain of Ch 8 20
Measure Crosstalk Coefficient

After running, file “scan******.coe” is saved in installation folder, thereinto instrument number is correspondence with *. In interface of run, pop up the upper window after run, user may select “Cancel” to quit measure, and may resume the upper produce to measure. Again(In order to assure correct data, crosstalk is required to measure twice) User can see dye in “Crosstalk Dyes Measured (T)…” of “System Parameters (P)” pull-down menu., during checking, please confirm that Default.ser is in installation directory.

Caution: To selected dye name does not correspond with actual dye, which causes wrong data.

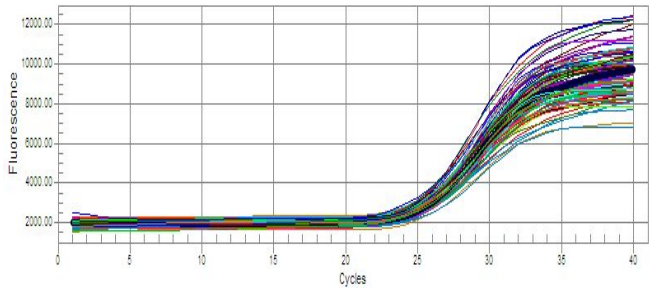
Because spectrum overlap of dye is large between channel F1 and channel F2(such as hex, tamra), crosstalk does not measure. Generally, user use one from F2,F3.

User may select reagent,which is single character and pure dye, of one or more channel to measure at the same time, and may add and cover, the saved file name: gain******.coe and scan******.coe, thereinto instrument number is correspondence with *. When measuring, operate software according to prompt, user may select dye name or define new dye name, set “gain” to fit value of channel when running.

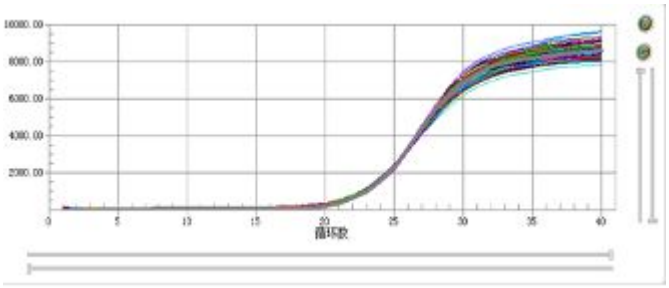
The reagent volume is 40μl, and it takes about 45min 85min during measure.

Flourescence Calibration

To open amplification result of FAM which includes the same concentration. Because of heterogenicity of fluorescence detection among wells, discreteness of CT value is obvious. There are discrepancy in baseline of different wells and in actual fluorecent gain. "Fluorescence Calibration" is to remedy heterogenicity of fluorescence increment.

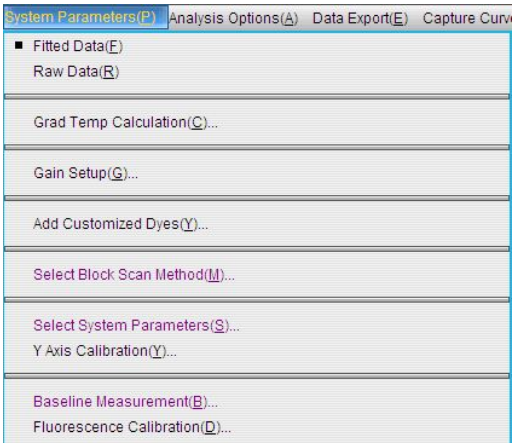


After uniformity calibration of fluorescence, discreteness of CT value is improved obviously.



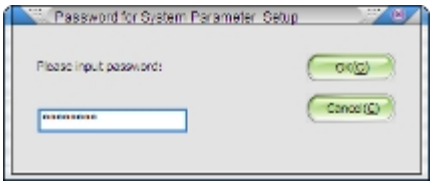
The following is calibration procedure:

In interface of quantitative analysis, to import analysis result, and to select the "Fluorescence Calibration" of the "System Parameters" pull-down menu.

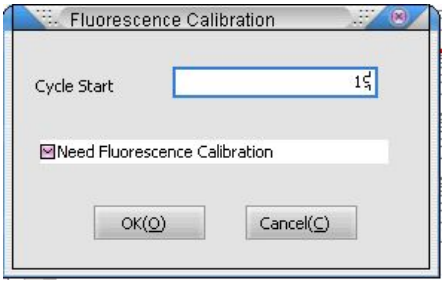


Caution: To delete file "*.prp" from installation directory before calibration.

To input password "bioerpcr" in the following window.



To input the cycle start in the following window (To select train cycle of fluorescence rise point, generally,select cycle 1-3 after rise point), and select "Need Fluorescence Calibration", then click "OK". System bases on fluorescence data of three sampling pionts of every well which is from start cycle, and caculate calibration coefficient automatically, then calibrate fluorescence uniformity of the result. Calibration coefficient of every well is saved as default file. When openning new file of result(The result must correspond with serial number of instrument), system can calibrate automatically according to saved calibration parameter, then discreteness of CT is improved substantially.



Causion: In order to get better result, user may calibrate again under the said situation. Do not continuously calibrate different cycle points when file "*.prp" has made.

File information

After opening a result, click "File info. (N)…" of "System Parameters (P)" pull-down menu to pop up dialog box, in which display the file name from the data file, and the file name is with instrument number and all modification parameters.

If there is no opening file, "File info." is under unusable state.

Less common items of system parameters

In "System Parameters (P)" pull-down menu, there are items that are used at ex-factory, as follows: select system parameters, Y axis calibration, baseline measurement, crosstalk measurement, crosstalk dyes measured.

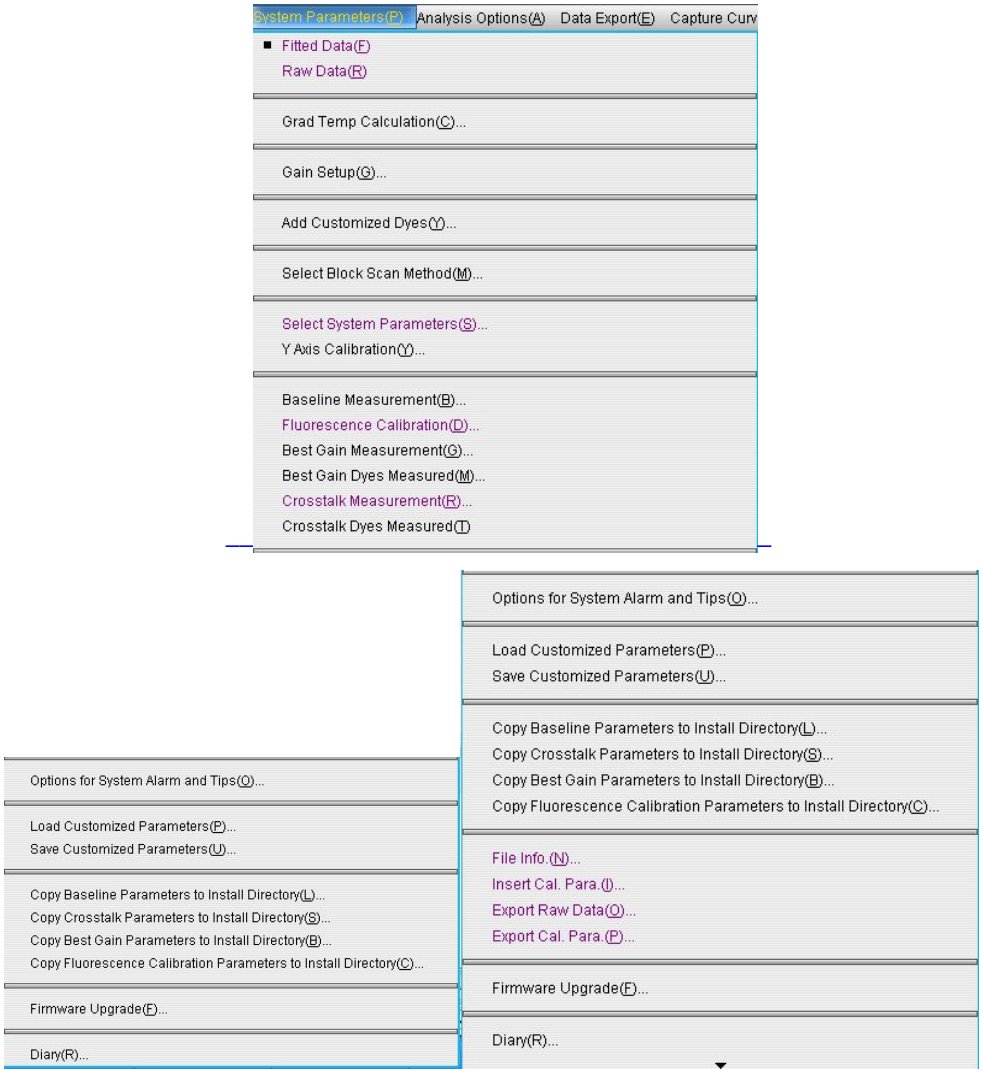
In "Select System Parameters", there are X origin calibration, measure gain ratio and crosstalk coefficient, clear run time, write machine serial NO. , read machine serial NO., write PMT parameters, read PMT parameters. These items can be used if instrument is running. In

addition, if you want to use these functions, you must enter password, Password has been set at ex-factory, you may ask manufacturer for password directly.

"Y Axis Calibration" means to calibrate Y axis automatically, This item can be used if instrument is running. In addition, if you want to use this function, you must enter password, Password has been set at ex-factory, you may ask manufacturer for password directly.

"Baseline measurement" includes two items: baseline measurement, substract baseline. If selecting baseline measurement, you may measure baseline of instrument automatically, and calibrate baseline automatically, results will be saved automatically in file "baseline******.b96" under install directory. If selecting substract baseline, system will carry out order of cutting baseline value in baseline parameter file "baseline******.b96" when fluorescence curve appers. Otherwise, system will not operate cancelling background. This item can be used if instrument is running. In addition, if you want to use this function, you must enter password, Password has been set at ex-factory, you may ask manufacturer for password directly.

"Insert Cal. Para", "Export Raw Data" and "Export Cal. Para" are used to deal with data by company, and user need not use these function.



System Parameters pull-down menu

~~Running of detection program file~~

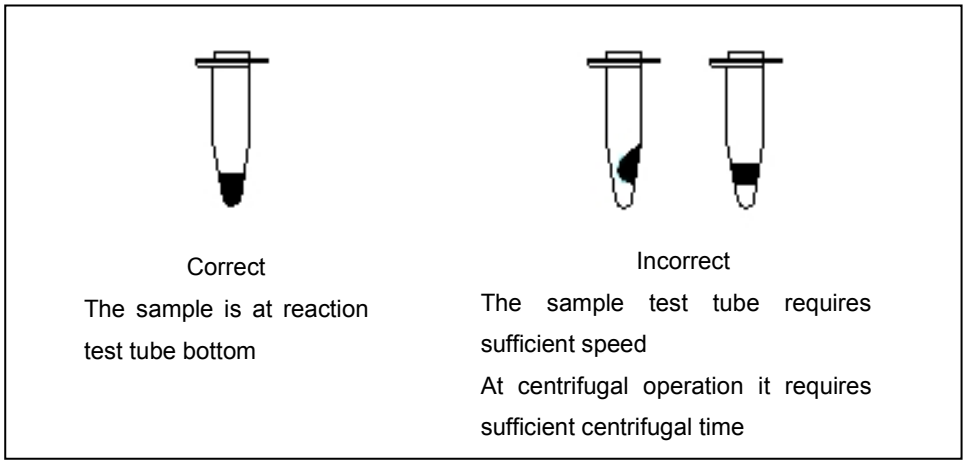
~~Caution:~~ ~~Before start, make checks and correctly start the system. The green lamp of run switch shall light on and the system shall be at running state.~~

~~Caution:~~ ~~Before running of program, the module shall be smoothly pushed to send locking sound and the alarm lamp is not on. If the module is pulled out or is improperly pushed, the software will show prompt and the alarm lamp will light on. At this case, temperature program can run but the fluorescence scanning data would become invalid.~~

3.1 Preparation for reagent sample

- Preparation for reagent: LineGene 9600 series fluorescent quantitative PCR detection system adopts 0.2ml centrifugal test tube to place reagent sample and 10μl～50μl is suggested for sample optimal reaction system.
- Optic lucid tube on bottom such as normative single valve, calandria, full apron plate, and so on, are allowed in strument.
- Centrifugal operation: Before placing into the instrument, the test tube with reagent sample shall be subjected to centrifugal operation to ensure that the reagent is at test tube bottom and the inside is free of bubble.

- To insert test tube: If the sample quantity is less than well quantity of module , the sample test tubes shall be evenly distributed in module well as far as possible, so as to make the hot-lid steadily compress on the top of test tube during running. The load of module shall be even so as to ensure even and consistent temperature change of each test tube.


Correct
The sample is at reaction test tube bottom
Incorrect
The sample test tube requires sufficient speed
At centrifugal operation it requires sufficient centrifugal time

Correct position of sample in test tube

3.2 Start Run

- Click **Start Run**

※The default running interface is florescence curve

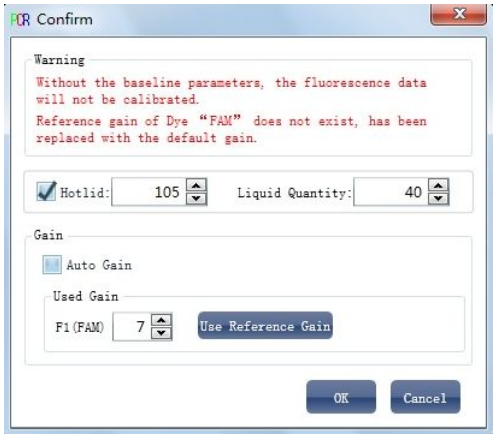
- Operating confirmation

a. Modify hotlid temperature and liquid quantity

b. Gain parameter setting

c. Target florescence value setting

※If necessary, the user can modify above parameters directly in this window.



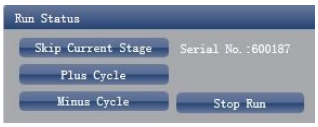
- After it starts running, the user can:

a. Skip the current stage

b. Plus cycle

c. Minus cycle

d. Stop run



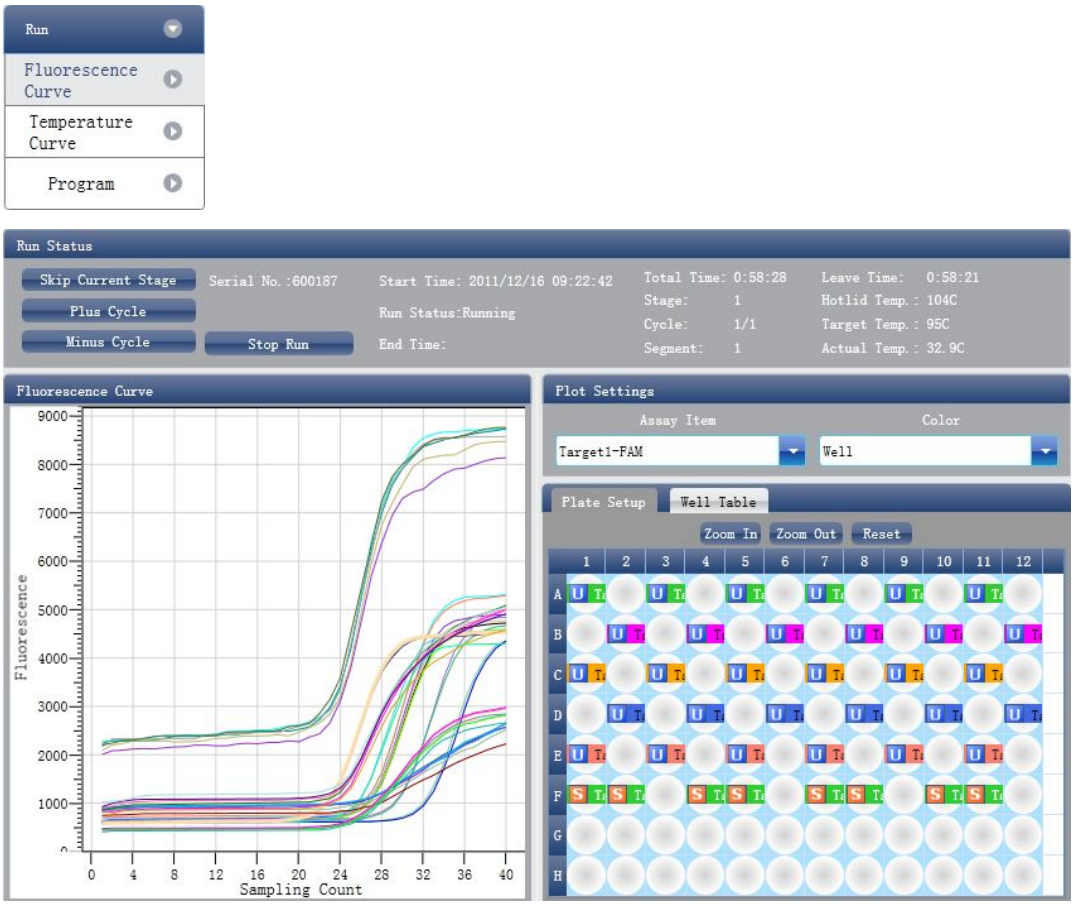
- Plot display setting

a. Assay item

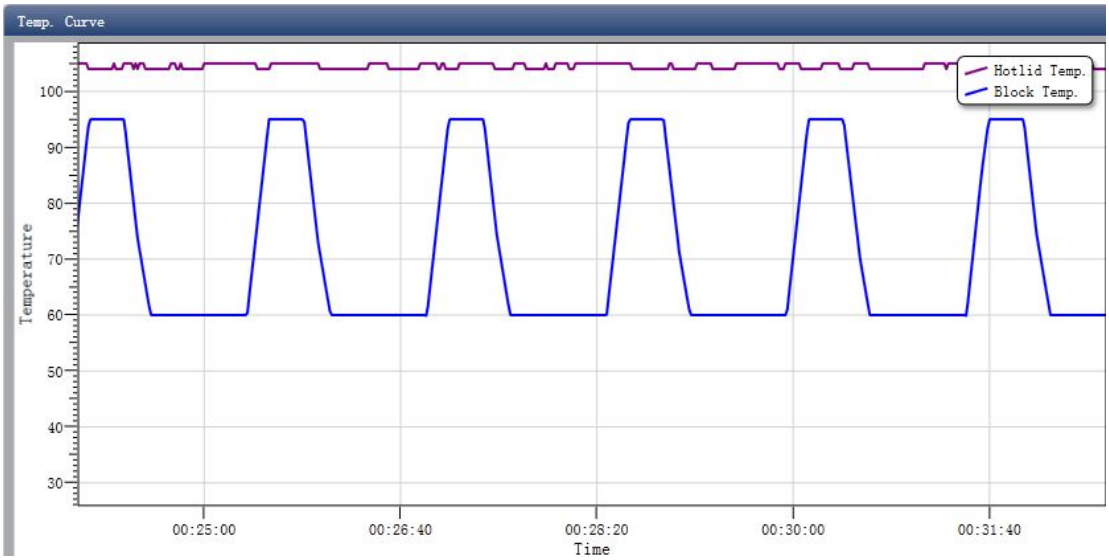
b. Plot color

3.3 Monitor Operation

- Monitor florescence curve: click **Florescence Curve**



- Monitor temperature curve: click **Temperature Curve**



3.4 Program Setting

The user can only check the program setting but cannot make modification.

~~Time-temperature display during running~~ 3.5

Working state indication lamps on instrument

The panel at upper left of instrument is fixed with 3 state indication lamps and they are related with system state during running of program:

- Running: The indication lamp lights green, which denotes that the entire machine is under program running state.
- Alarm: The indication lamp lights yellow, which denotes that the module is not fully pushed in and the hook is not fastened.
- Error: The indication lamp lights red, which denotes that the instrument is in troubles.

Caution: For prolonged shutdown after end of program running, set the power switch at instrument's rear bottom board at "OFF" and cut off power supply. After turning on power, the hot-lid and module will run as per default state.

The front cover of instrument is fixed with a self-locking key to control energizing of its inside control system:

- Run Switch: running/standby switch.
- After pressing this key, the green loop lamp lights on instrument inside system is energized and the user is allowed to run the program.
- After pressing this key again, the key will spring out, the green loop lamp lights off, instrument inside system is de-energized and the system is under standby.

Caution: The run switch is for user's easy operation and is merely used for temporary or

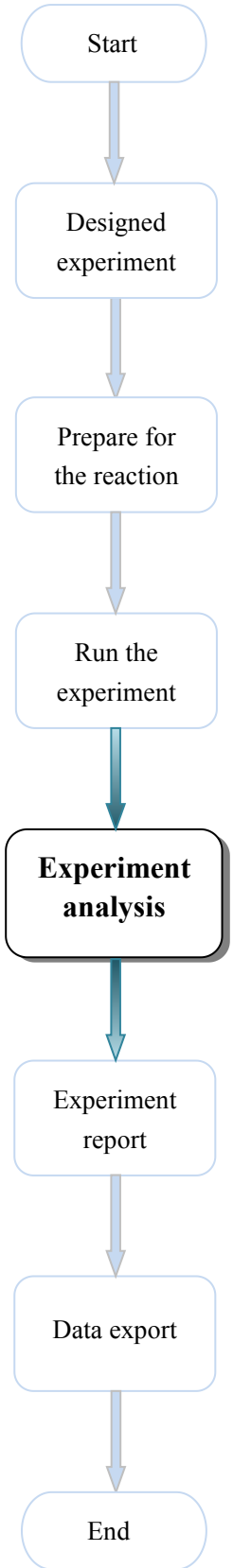
short time closing control system. When the system is under standby state, the instrument inside AC circuit is live.

3.4.1 Prompts likely occurring during running

- Hot-lid temperature sensor alarm prompt
- Sink temperature sensor alarm prompt
- Environmental temperature sensor alarm prompt
- Module temperature sensor alarm prompt
- Module sensor short-circuit or short-circuit alarm prompt

Caution: In case of temperature alarm display during running of program, the PCR detection system running program shall be terminated, the instrument shall be switched off and then re-started.

4. Experiment Analysis

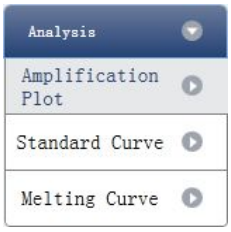


This section describes how to view the experiment analysis result after the operating experiment and adjust parameter reanalysis. This section covers the analysis of amplification curve and standard curve, adjusting parameter reanalysis and parameter importing.

4.1 Check Results

4.1.1 Check the Amplification Plot

- Click **Analysis▶ Amplification Plot**



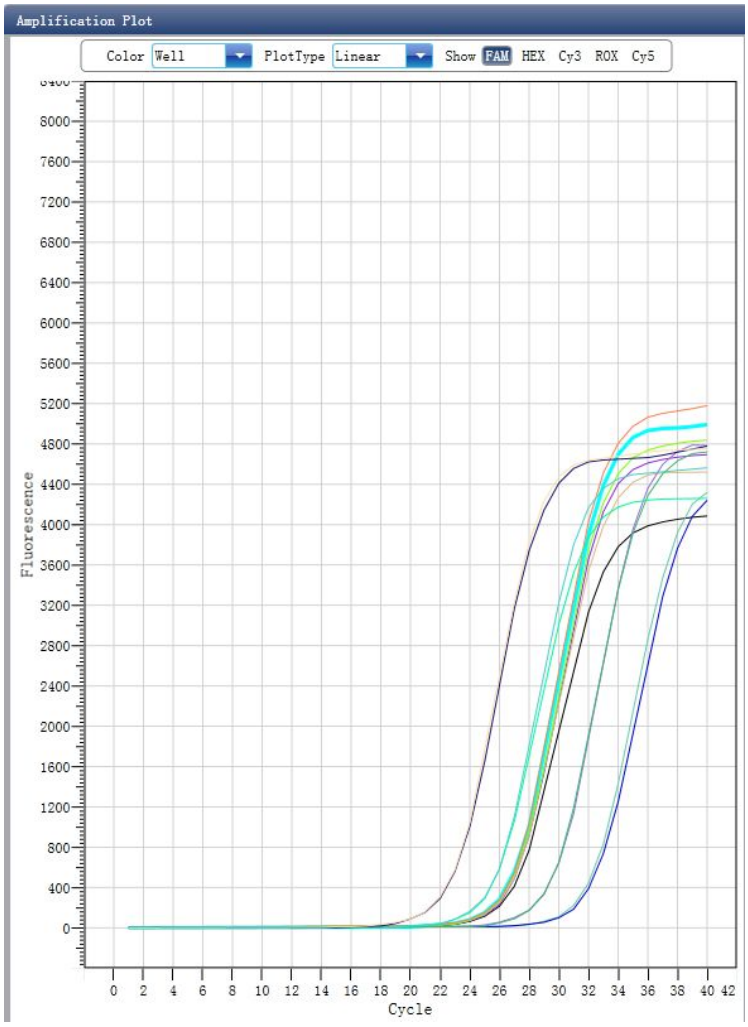
- Check the amplification curve

  a. Set up color

  b. Set up plottype

  c. Set up show dye

  ※When the background color of a dye name is blue, it means to be displayed; while white indicates not to be displayed.



- Check the reaction plate

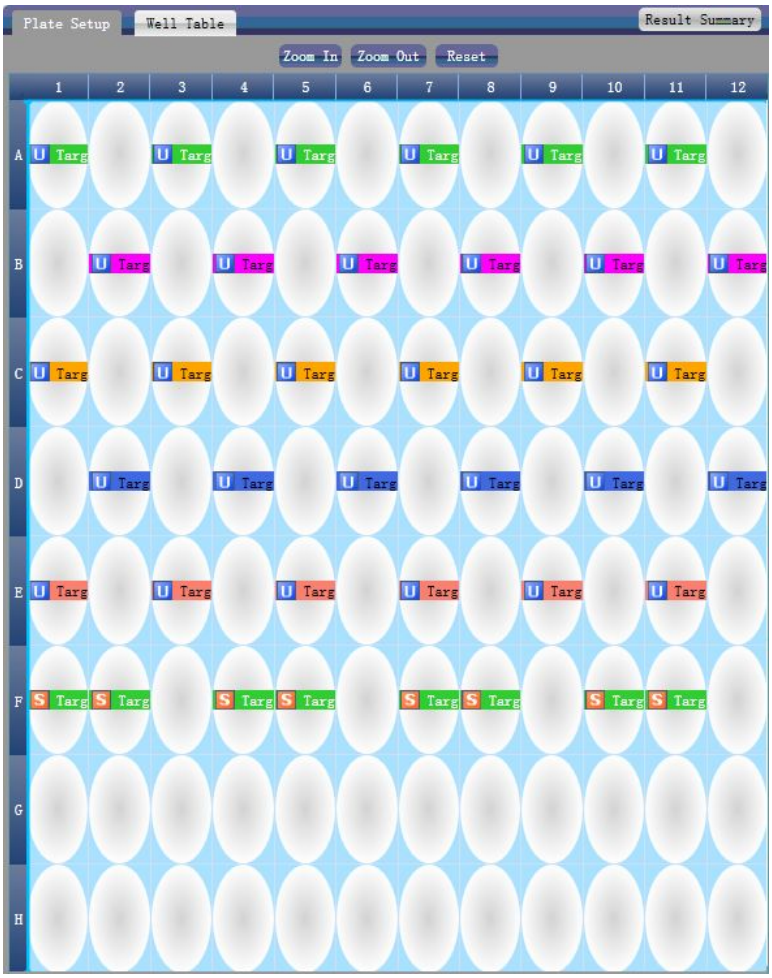
  a. Select relation plate hole site and check corresponding hole site curve

  ※The default is all hole sites are selected

  b.Zoom In, Zoom Out and Reset the reaction plate

  c. Check well table information

  d. Check results summary



- Set up assay

  a. Set up Assay

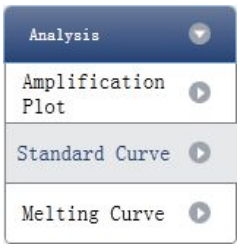
  b. Set up Threshold

  c. Set up automatic baseline

  ※When the threshold value is not automatic, the user cannot set up the automatic baseline

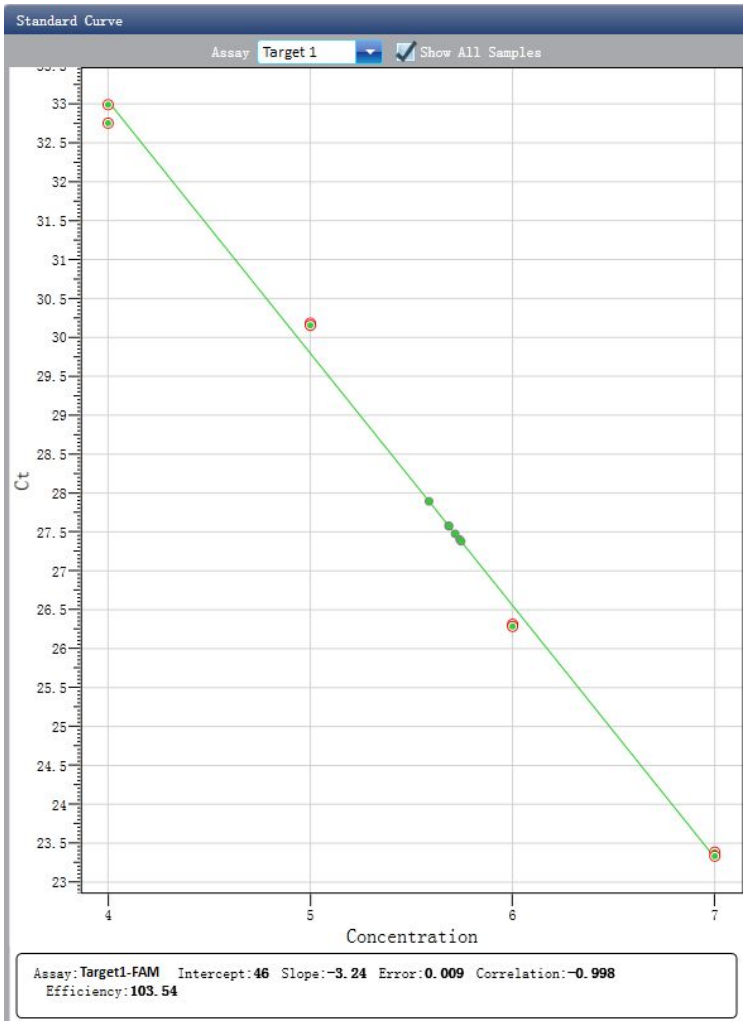
4.1.2 Check Standard Curve

- Click **Analysis▶ Standard Curve**



- Check standard curve

  a. Set up assay



- Check the reaction plate

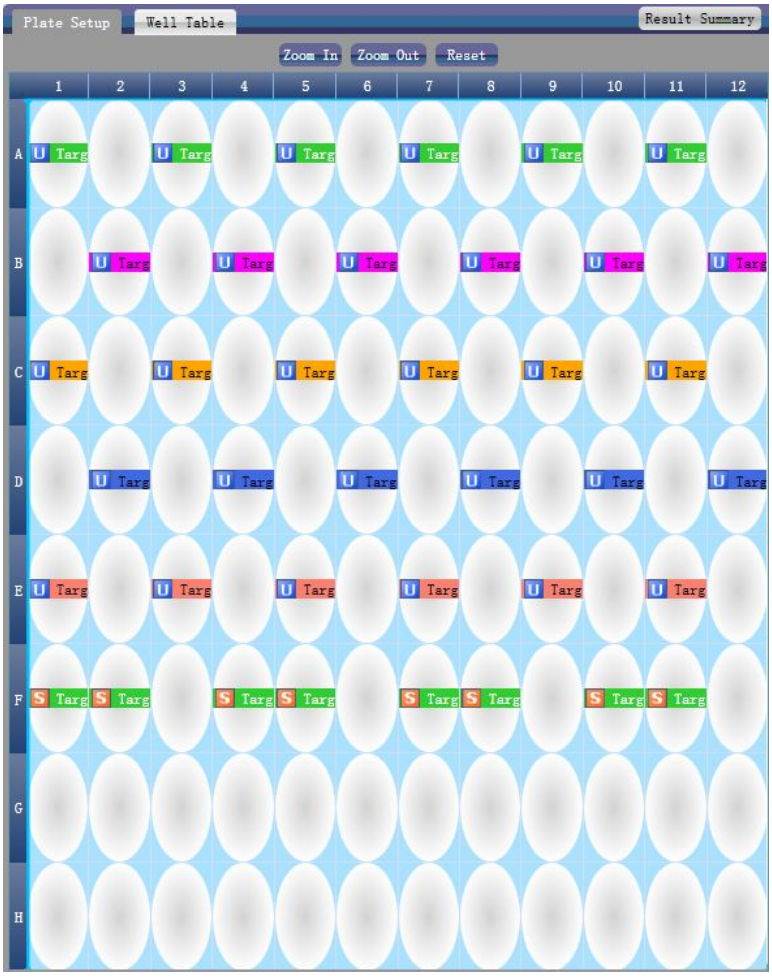
  a. Select relation plate hole site and check corresponding hole site curve

  ※The default is all hole sites are selected

  b.Zoom In, Zoom Out and Reset the reaction plate

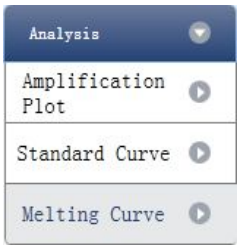
  c. Check well table information

  d. Check results summary



4.1.3 Check Melting Curve

- Click **Analysis▶ Melting Curve**

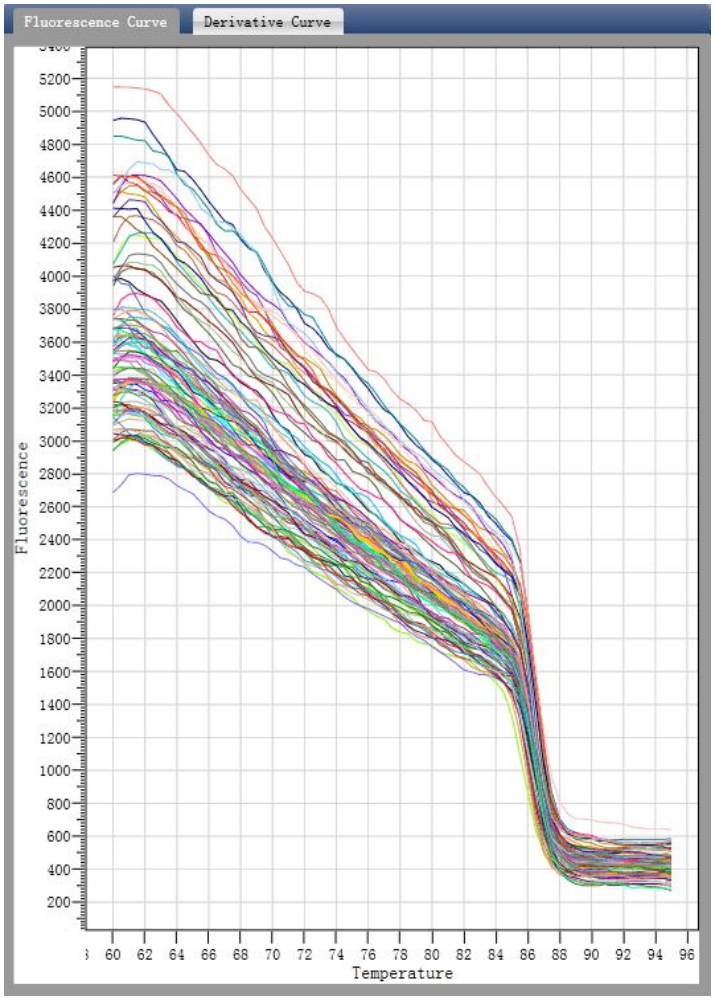


- Check the melting curve

  a. Check the fluorescence curve

  b. Check the derivative curve

  c. Set up color



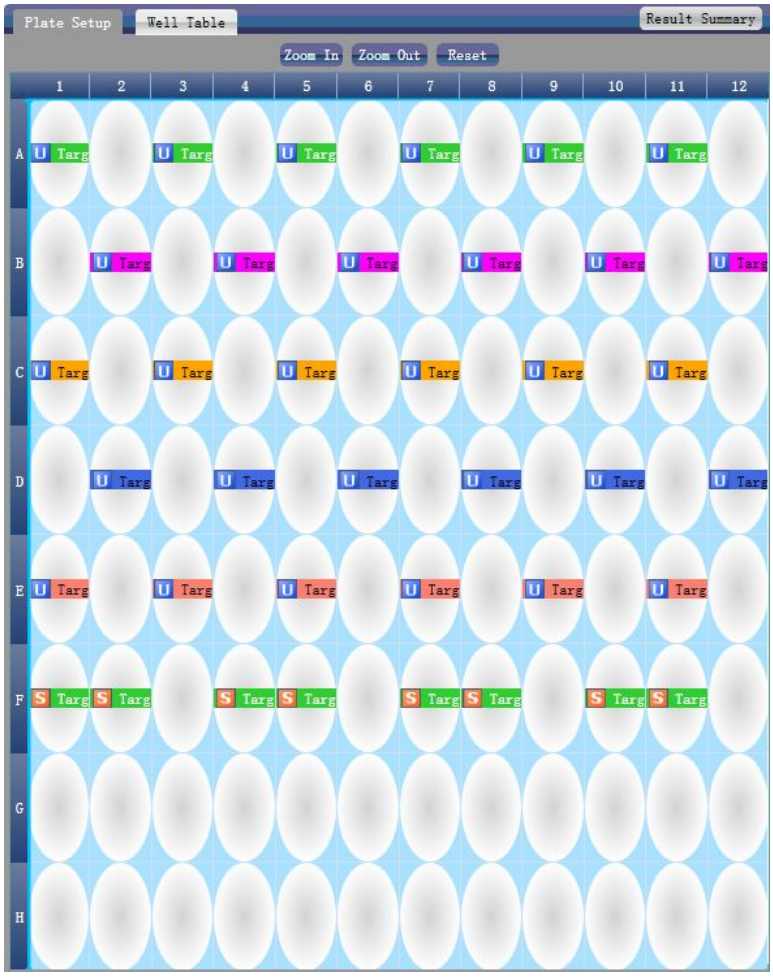
- Check the reaction plate

  a. Select relation plate hole site and check corresponding hole site curve

  ※The default is all hole sites are selected

  b. Zoom in, zoom out and reset the reaction plate

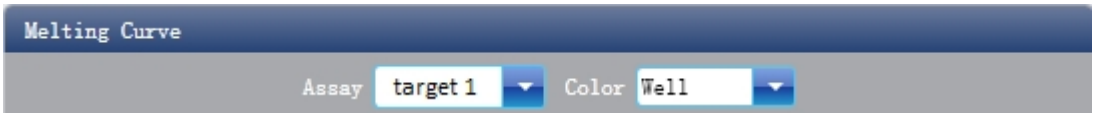
  c. Check well table information



- Set up assay

  a. Set up assay

  b. Set up color



4.2 Adjust Parameter Reanalysis

- Click **Analysis Settings**▶the Analysis Settings dialog box will pop up

  a. Adjust the start cycle and end cycle of the baseline

  b. Adjust Ct analysis algorithm

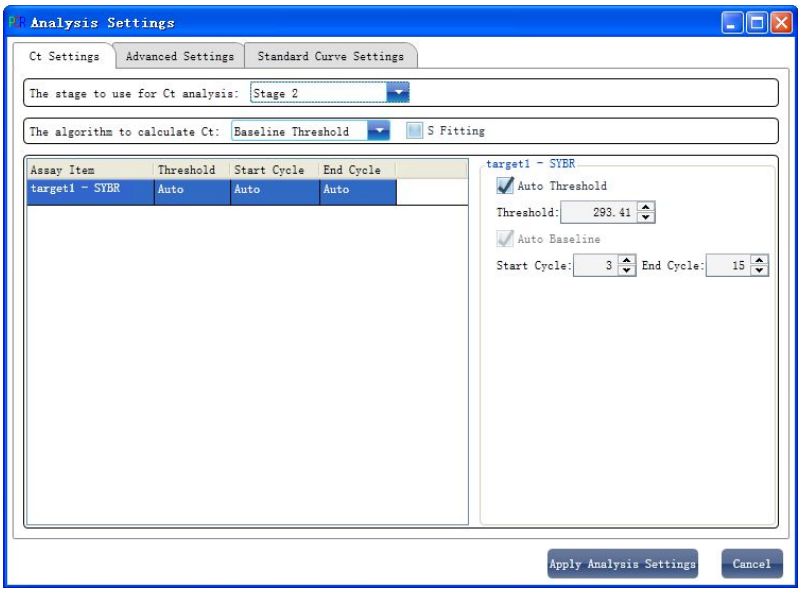
  c. Set up the use of S fitting

  d. Set up the stage to use for Ct analysis

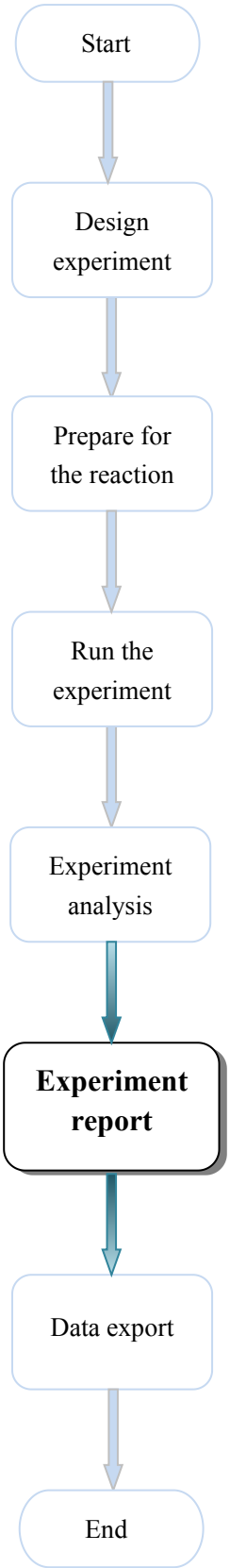
  e. Set up the automatic threshold value

  f. Advanced setting

  g. Standard curve setting


Analysis Settings
Ct Settings
Advanced Settings
Standard Curve Settings
The stage to use for Ct analysis:
Stage 2
The algorithm to calculate Ct:
Baseline Threshold
S Fitting
Assay Item
Threshold
Start Cycle
End Cycle
target1 - SYBR
Auto
Auto
Auto
target1 - SYBR
Auto Threshold
Threshold:
293.41
Auto Baseline
Start Cycle:
3
End Cycle:
15
Apply Analysis Settings
Cancel

5. Experiment Report



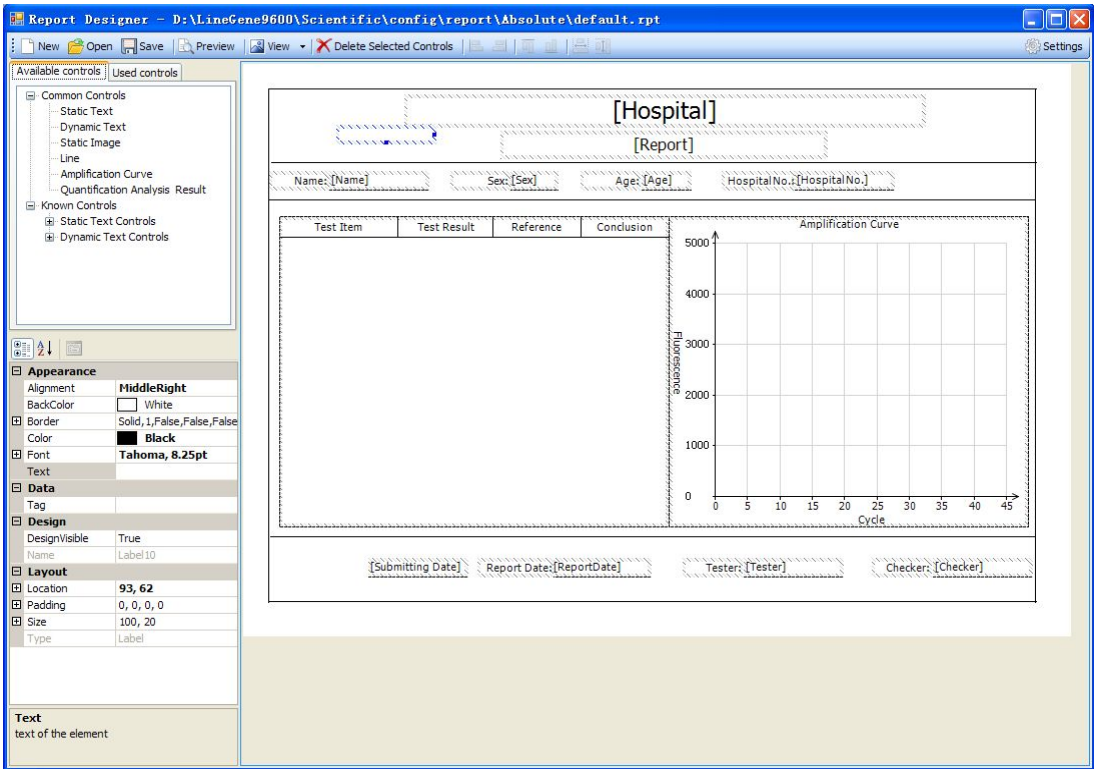
This section describes how to print experiment report and covers report template designing and print setting.

5.1 Report Template Designing

Click **Report ▶Report Template Editor▶**the Report Designer window will pop up

The report consists of controls and the user can add, modify and delete controls.

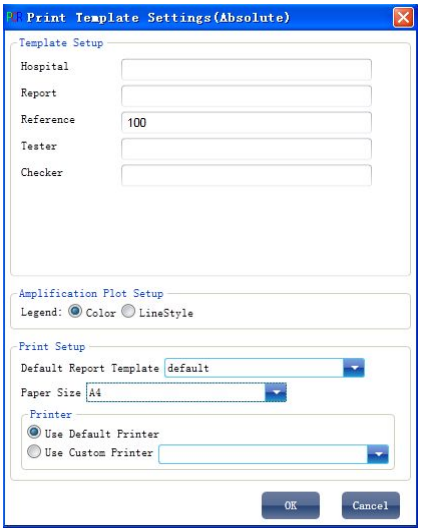
Available controls include Static Text, Dynamic Text, Line, Static Image, Aamplification Curve and Quantification Aanalysis Result.



5.2 Print Setting

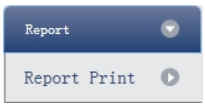
Click **Report ▶Print Template Setting▶**the Print Template Setting window will pop up

The user can set up the hospital name, report name, reference value, tester, checker, amplification plot setup, default report template and paper size.



5.3 Report Printing

- Click **Report▶Report Print**



- Report print setting

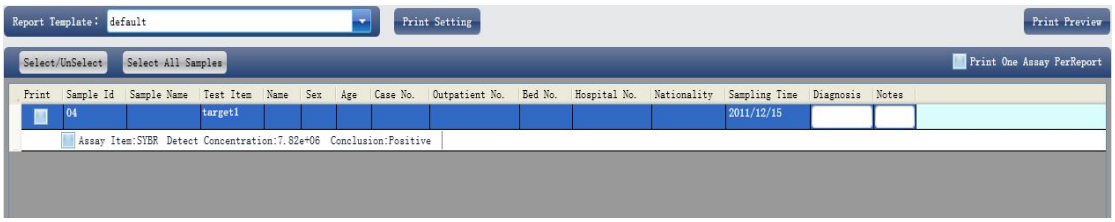
  a. Set up report template

  b. Print setting (please refer to Section 5.2)

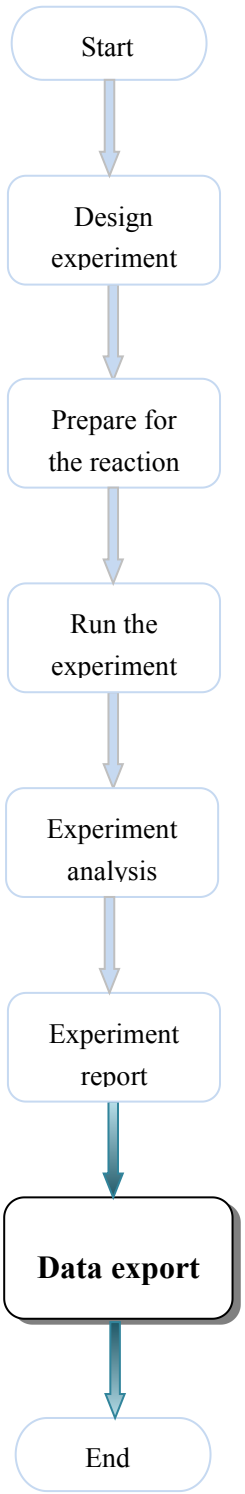
  c. Select print items

  d. Print preview

  e. Print the report



6. Data Export



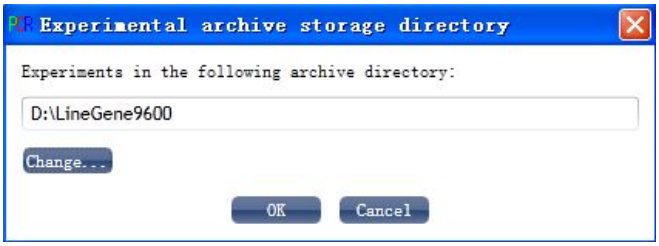
This section describes how to export data and covers exporting to the database, experiment filing and exporting the experiment data to EXCEL

6.1 Export to Database

Click **Data Summary**▶**Export to Database**▶the save file dialog box will pop up▶save the exported database file

6.2 Experiment Filing

- Click **Data Summary** ▶ **Archived Experiment Diretory** ▶ the Experimental archive storage directory window will pop up▶set up the storage path of file



- Experiment filing

  Click **Data Summary**▶**Archived Experiment** ▶export the filed experiment file

  ※The suffix of filed experiment file is .fqh

6.3 Export Experiment Data to EXCEL

Click **Data Summary**▶**Export Experiment to EXCEL**▶set up **Well Horizontal (**set up **Well Vertically)** ▶the exported experiment data will generate EXCEL file

Chapter 5 Tool Usage

1. Gain Setting

Gain Setting tools are used to set up gain modes.

Click **Tools▶ Gain Setting▶**the following window will pop up

Gain setting can be set up as: **reference gain, custom gain and auto gain**

※In the mode of **Custom Gain**, the user can modify the gain value.

2. Target Library

Target Library tools are used to set up the inspection libraries of absolute quantitative.

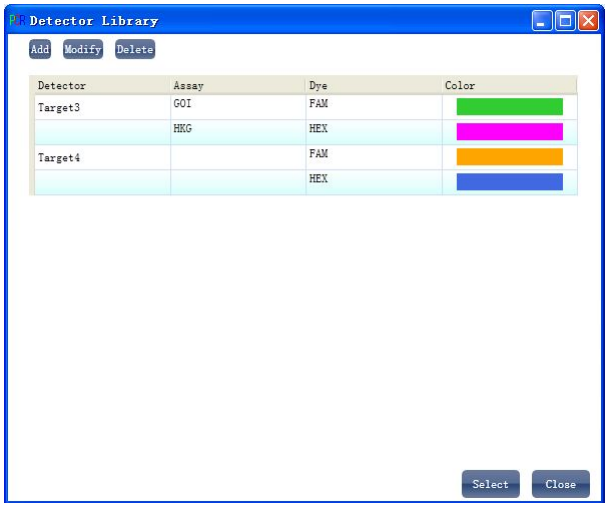
Click **Tools▶ Target Library** open the following window

The user can:

a. Add Detector

b. Modify Detector

c. Delete Detector



3. Customized Dyes

Customized Dyes tools are used to set up existing dyes and newly added dyes.

Click **Tools▶ Customize Dyes ▶**open the following window

The user can:

a. Create dye

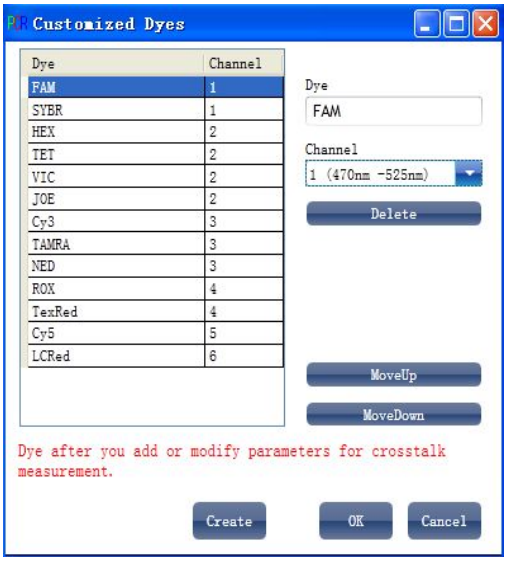
b. Modify dye name and channel

c. Delete dye

d. Move dye upward

e. Move dye downward

※After adding new dyes or modifying dyes, the user should conduct crosstalk parameter measurement.



4. Customize Columns

Click **Tools▶ Customize Columns** ▶the following window will pop up

The user can:

a. Add columns

b. Delete columns

c. Modify column name

5. Column Selection

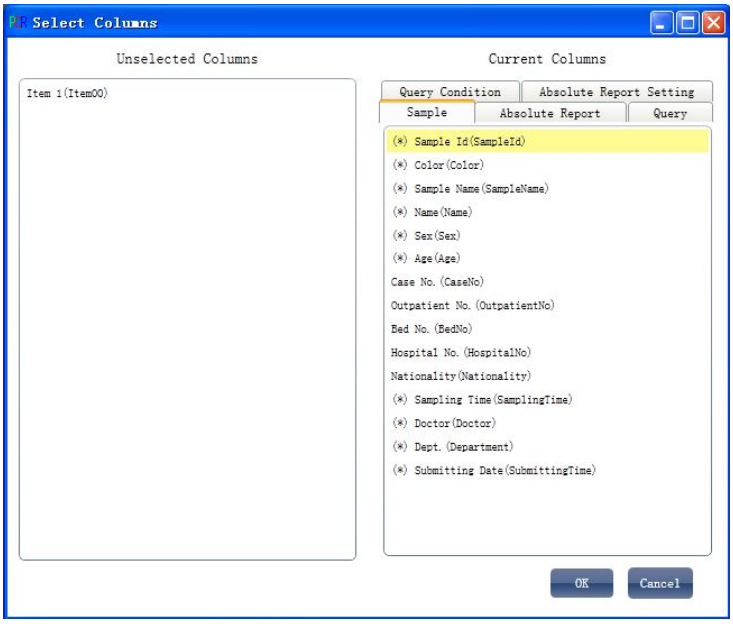
Select Columns tools are used to add the new columns in above section into current existing columns, or remove existing columns in current column.

Click **Tools▶ Select Columns ▶**the following window will pop up

※a. Current existing column items include sample, absolute report, absolute report setting, query and query condition

b. Double click column can add or remove a column

c. Column with (*) indicates it cannot be removed



6. Sample Column Library

Sample Column Library tools are used in the experiment design phase. The user can selection the definition of contents in the drop-down box when setting up sample information.

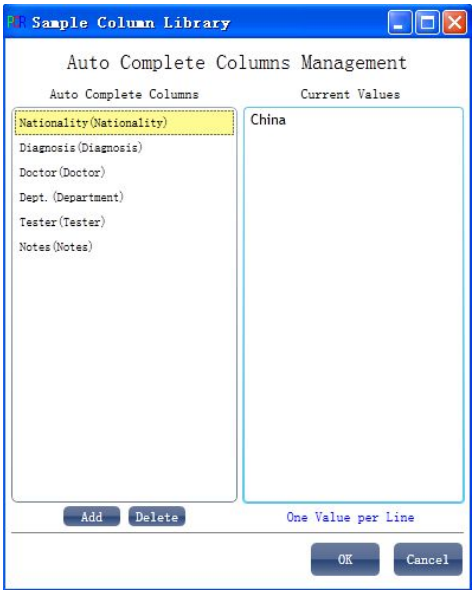
Click **Tools▶ Sample Column Library ▶**the following window will pop up

The user can:

a. Add columns

b. Delete columns

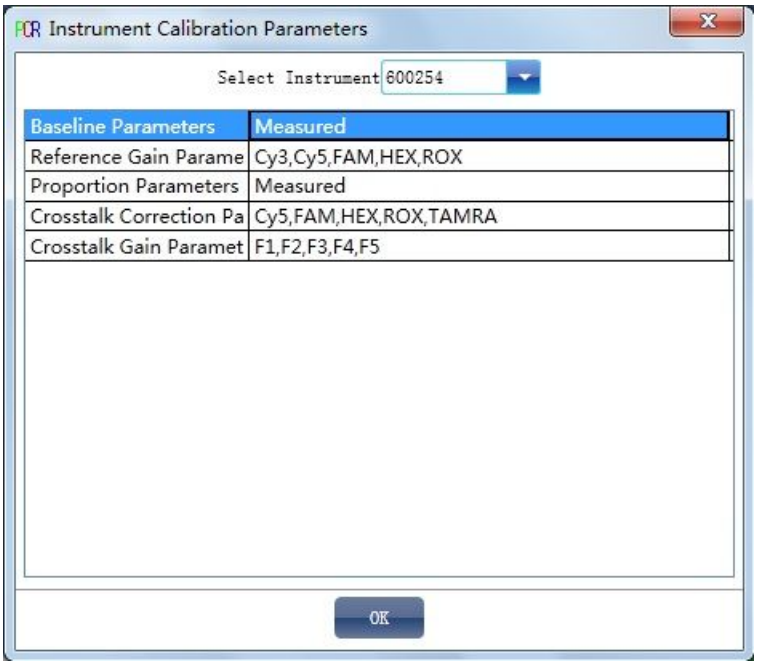
c. Edit the columns content



7. Instrument Calibration Parameters

Instrument Calibration Parameters tools are used to calibrate instrument parameters.

Click **Tools▶ Instrument Calibration Parameters▶**the following window will pop up



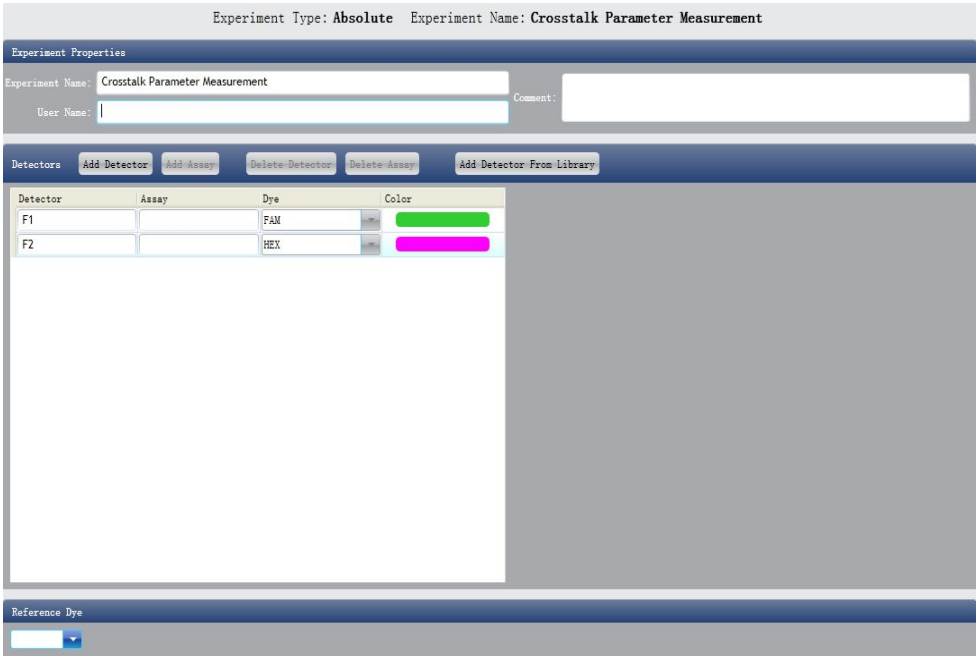
8. Measure Crosstalk Calibration Parameters

Measure Crosstalk Calibration Parameters tools are used to measure crosstalk correction parameters.

Click **Tools▶ Measure Crosstalk Calibration Parameters ▶**the following window will pop up

The user can add and modify the channels to be tested and dyes according to his needs;

upload corresponding reaction plates and operate the experiment; when the experiment is over, the system will automatically save the crosstalk correction parameters.

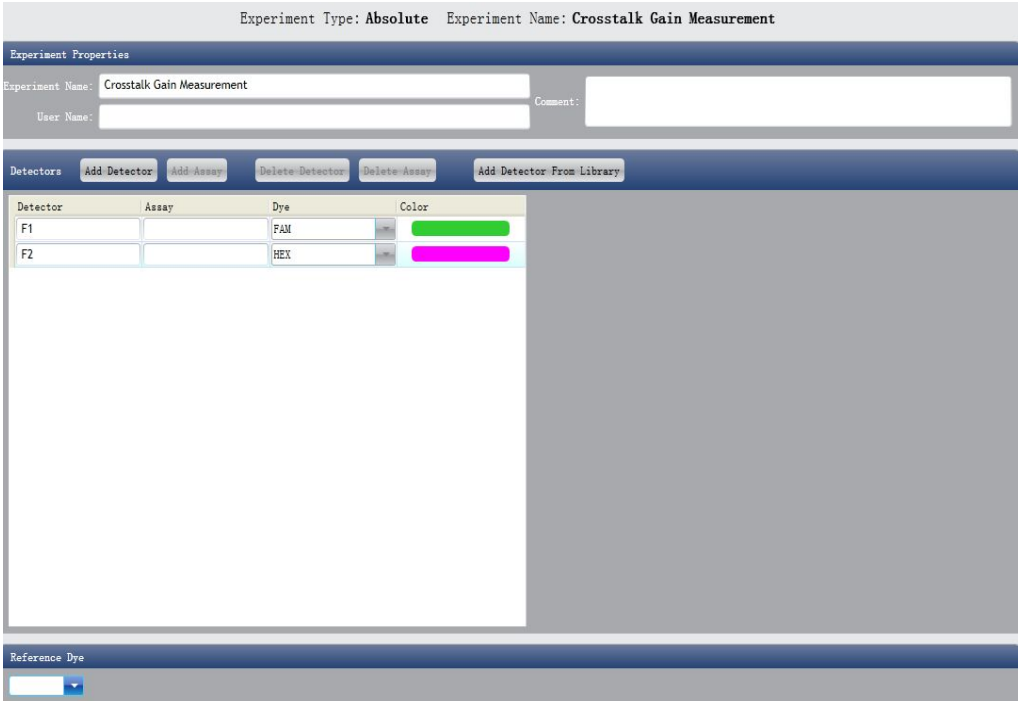


9. Crosstalk Gain Parameter Measurement

Crosstalk Gain Parameter Measurement tools are used to measure crosstalk gain parameters.

Click **Tools▶Measure Crosstalk Gain Parameters▶**the following window will pop up

The user can add and modify the channels to be tested and dyes according to his needs; upload corresponding reaction plates and operate the experiment; when the experiment is over, the system will automatically save the crosstalk gain parameters.



10. System Maintenance

System Maintenance tools are used for system maintenance.

Click **Tool Menu**▶ **System Maintenance**▶the Password Input box will pop up▶input the correct passwords▶conduct the following setting:

a.Y-axis commissioning

b. X-axis origin calibration

c. Machine serial number setting

d. Photomultiplier setting

e. Runtime zero clearing

f. Background measurement

g. Reference gain measurement

h. Fluorescence incremental calibration

11. Firmware Upgrading

Firmware Upgrading tools are used to upgrade the firmware.

The instrument by connection of RS232 communication wire with computer realizes its software update as follows:

- Set its rear MODE update switch of communication box on the back of the instrument to right side Update, turn on power supply and connect serial port line. The instrument is in update status, In the panel, indicator light and trouble light are lighted in the same time, which is normal.
- Click **Tool Menu**▶**Firmware Upgrading**▶the following window will pop up

The user can:

a. Select serial ports

b. Select the BIN file to be upgraded

c. Upgrade

12. Convert Old File into New File

Convert Old File into New File tools are used to convert old files with the suffix of fqj or fqs into new files with the suffix of fqd.

Click **Tool Menu**▶ **Convert Old File into New File**▶the following window will pop up

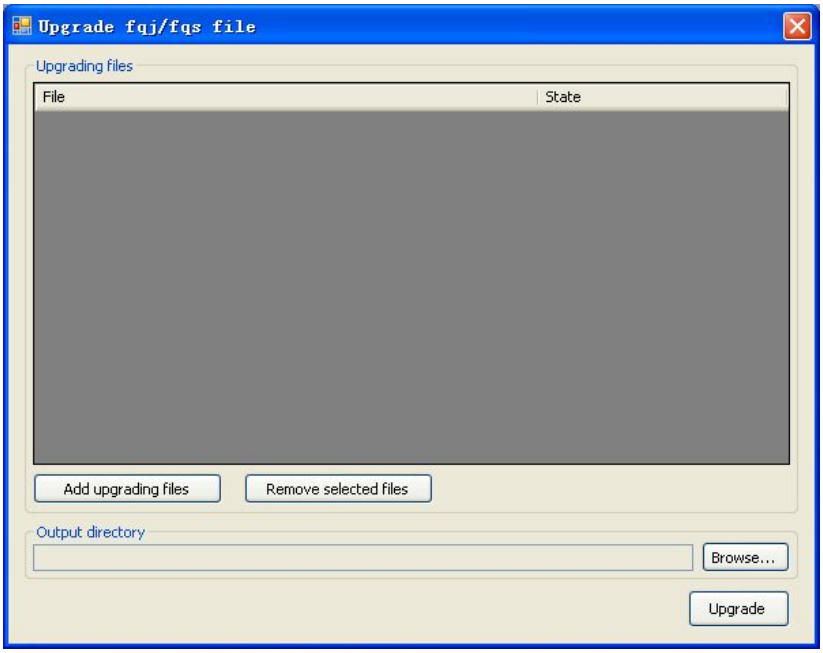
The user can:

a. Add files to be upgraded

b. Delete selected files

c. Select the output directory of new files

d. Upgrade



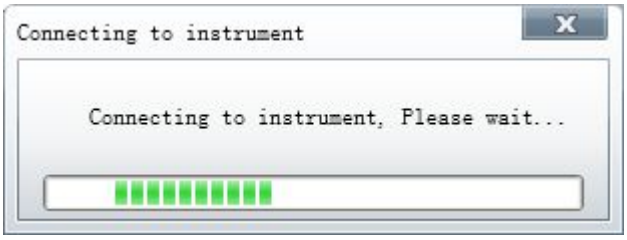
Chapter 6 Other Functions

1. Instrument Operation

Instrument operations include connecting the instrument, disconnecting the instrument and instrument information.

1.1 Connect Instrument

Click **Instrument**▶**Connect**▶select port number or select automatic port matching



When the instrument is connected, the icon on the status bar will be ; if the instrument is disconnected, the icon on the status bar will be .

1.2 Disconnect

Click **Instrument** ▶**Disconnect**▶disconnect currently connected instrument

1.3 Instrument Information

When the instrument is connected, the user can check the instrument information.

Click **Instrument**▶**Instrument Information**▶the following dialog box will pop up

Instrument information includes instrument serial number, runtime, currently connected ports, whether the experiment is in operation.

2. Data Query

Data Query is used to query the data already exported to the database.

Click **Data Summary** ▶**Data Query**▶the following window will pop up

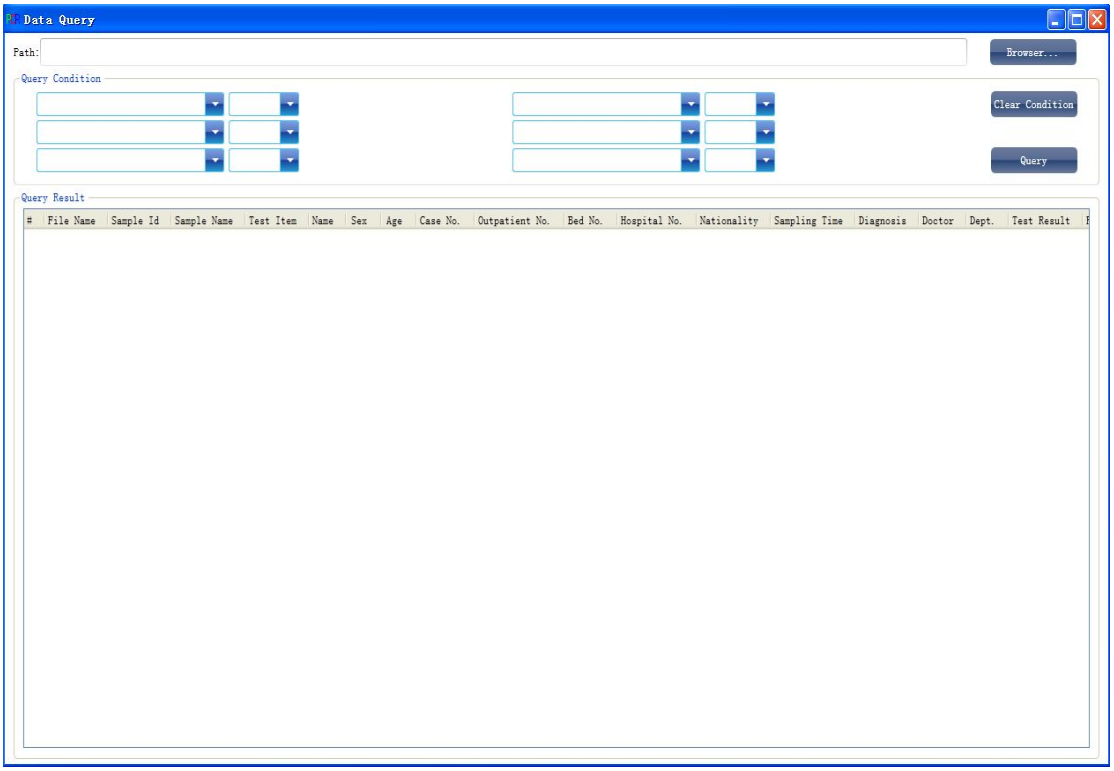
The user can:

a. Select database files

b. Set up query condition

c. Query

d. Clear all query conditions


Data Query
Path:
Browser...
Query Condition
Clear Condition
Query
Query Result
File Name Sample Id Sample Name Test Item Name Sex Age Case No. Outpatient No. Bed No. Hospital No. Nationality Sampling Time Diagnosis Doctor Dept. Test Result

3. Open and Save File

- Open a file

  Click **File►Open►**the Open File dialog box will pop up

  The user can open experiment file (*.fqd), experiment template file (*.fqt), experiment filing file (*.fqh) and quantitative experiment file (*.fqj) in old version.

- Save file

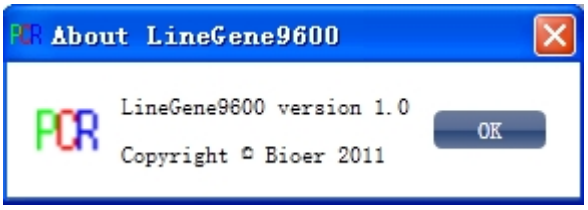
  Click **File►(Save/Save As/Save As Template)**

4. System Help

Click **Help ►Help Topics**

5. About

Click **Help ►About ►**the following window will pop up



Chapter 7 Maintenance

1. Regular cleaning

In order to ensure normal operation, detection and use, the instrument shall be regularly cleaned.

- To clean of outer surface: It shall be cleaned with soft cloth, and if necessary, soft cloth may be soaked with alcohol, distilled water or cleaning paste.
- To clean of module well: It may be cleaned with nail wipes which does not bring dust ~~accompanied brush and clean soft cloth,~~ and if necessary, they may be soaked with 95 percent~~a little~~ of absolute ethyl alcohol used in medicine ~~alcohol~~ or distilled water.

Warning!

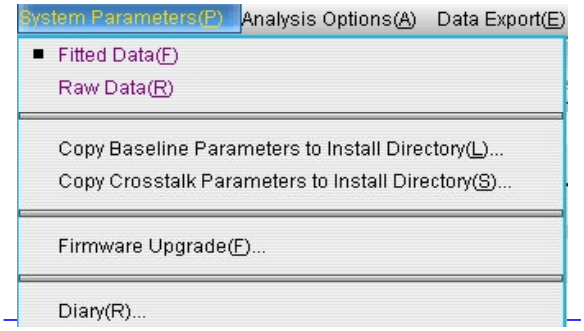
1. Before cleaning this instrument, the power supply shall be cut off.
2. At cleaning conical holes of the module, cares shall be take to prevent cleaning agent from dropping into the well.
3. The surface of this instrument shall not be cleaned with corrosive cleaning agent.
4. In order to avoid to scratch or damage optics in the wells, sharp and hard things are prevented to reach to wells of block.

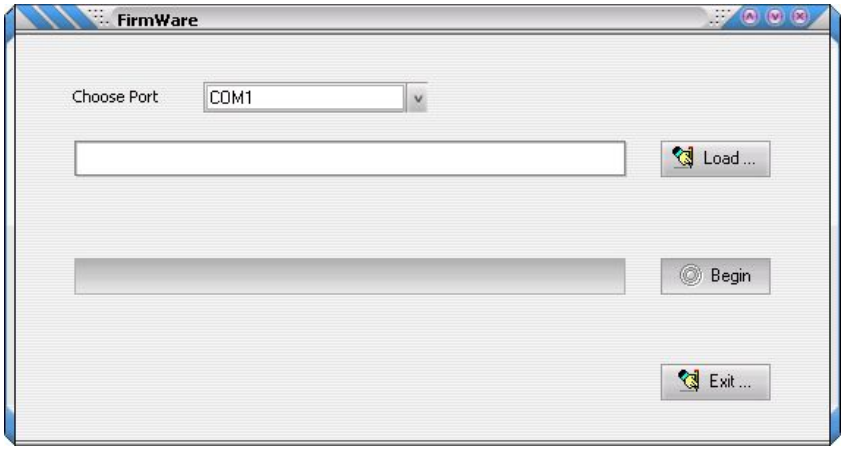
~~Software update~~

~~The instrument by connection of RS232 communication wire with computer realizes its software update as follows:~~

~~Set its rear MODE update switch of communication box on the back of the instrument to right side Update, turn on power supply and connect serial port line. The instrument is in update status, In the panel, indicator light and trouble light are lighted in the same time, which is normal.~~

~~Open LineGene 9600 software, select absolute quantification function module, and from the main interface of absolute quantification module click "Firmware Upgrade (F)…" of "System Parameters (P)" pull-down menu.~~





~~On the pop up dialog interface select the communicationserial port connecting instrument with computer.~~

~~Click "Load" and select update software (*.bin), which may be obtained from BIOER network or after service department.~~

~~To press "Begin" key to start update, if communication is successful, prompt sound will be heard. and Aafter the update, "Update Completed" interface will pop up, prompt sound will be heard..~~

~~Press "Exit" key to complete software update..~~

~~After power off, sSet the update switch to Normal at left side and normally use instrument after power on.e to end the host software update.~~

2. Analysis and elimination of troubles

No.	Trouble	Possible cause	Correction
1	The power switch at rear of instrument is set ON, but the instrument makes no response.	The run switch at front of instrument is not pressed, which shall be set "On" during running; otherwise the inside switching power will have no voltage output.	For working of instrument, its run switch shall be pressed and the green loop lamp shall light on to indicate energizing of the control system.
2	The module temperature runs normal, but the fluorescence detection makes no scanning	The fixing clamp is not removed or is not inserted and tightened to rear UNLOCKER well.	Remove fixing clamp and tighten to UNLOCKER well. (For transport, the instrument shall normally shutdown and fixing clamp shall be removed and then screwed into side well.)
3	Display of system parameters menu requires input of "Password".	The system parameters are for instrument manufacturer's inside calibration and require special accession password.	The function is unnecessary for the user and for calibration it shall contact manufacturer's service personnel.

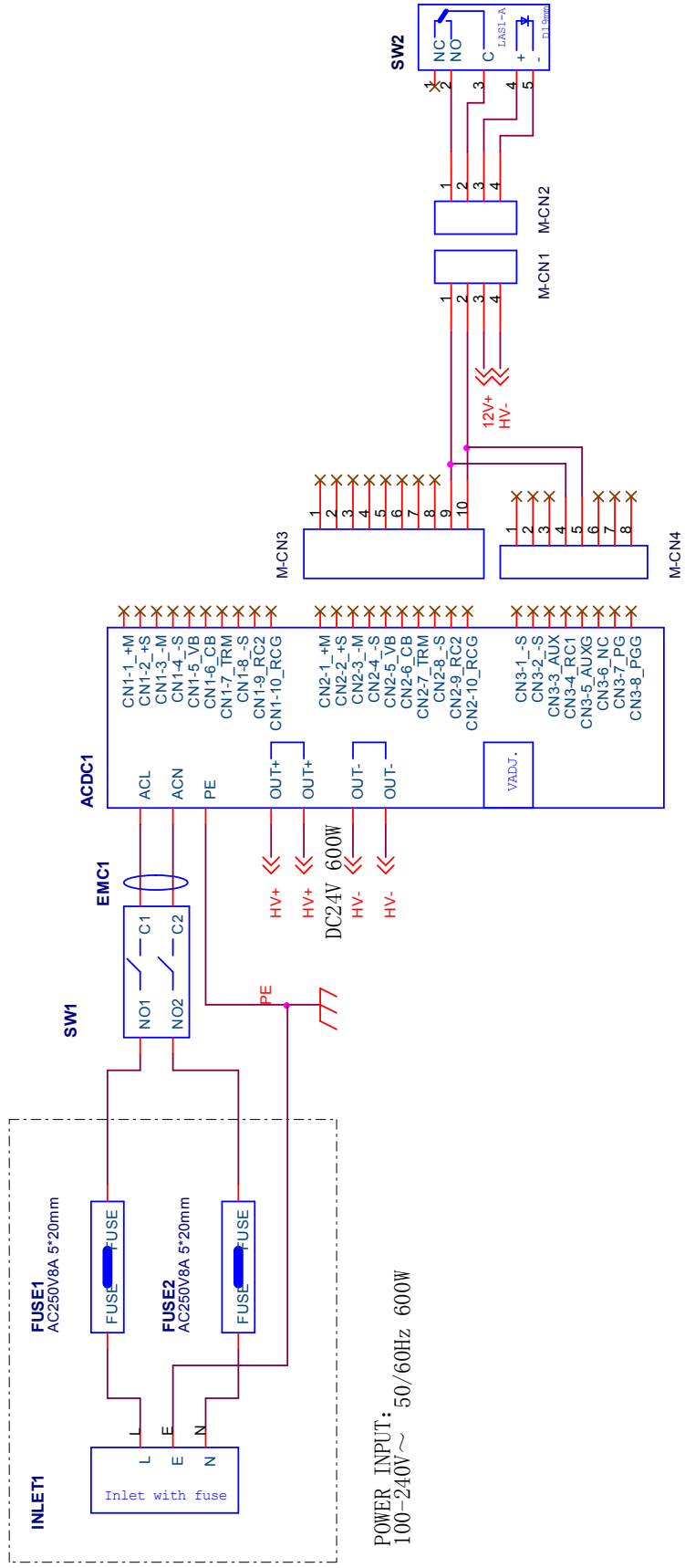
4	After turning on power switch the power lamp fails to light on	The run switch is not pressed	This switch is used for temporary turning on/off output power and is equivalent to “standby” function. For prolonged shutdown, the rear power switch shall be set “Off”.
		Power is not switched on.	Check and switch on power
		Burnt fuse	Replace fuse (250V 8A Φ5x20)
		Damaged switch	Replace switch
		other	Contact the supplier or manufacturer
5	At detecting sample position, the step motor fails to work and the communication fails.	Poor contact or damage of interface wire	Check, connect or replace interface wire
		The power switch is not turned on or is turned on only after program running	Turn on power switch and restart program
		The step motor or the drive is damaged	Contact the supplier or manufacturer
		The fixing clamp is not fully inserted.	Tighten it to UNLOCKER well, and re-turn on power after shutdown
6	After detecting sample position, the actual temperature displays 0°C or 100°C	The module temperature sensor is damaged. It accompanies panel red lamp alarm and software prompt, and instrument automatically stops running.	Contact the supplier or manufacturer
		The power switch is turned on only after program running.	Turn on power switch and restart program
		The program is searching communication port and during this period data would be not sent.	If the trouble still exists after researching, contact the supplier or manufacturer
7	Module temperature/raising/lowering rate obviously decreases or temperature control is incorrect.	The ventilation opening is blocked.	Clear the stem of the ventilation opening
		Loose connection wire	Contact the supplier or manufacturer
		The refrigerating sheet is damaged	
		Fan is damaged or fails to run	
		The temperature sensor is damaged	

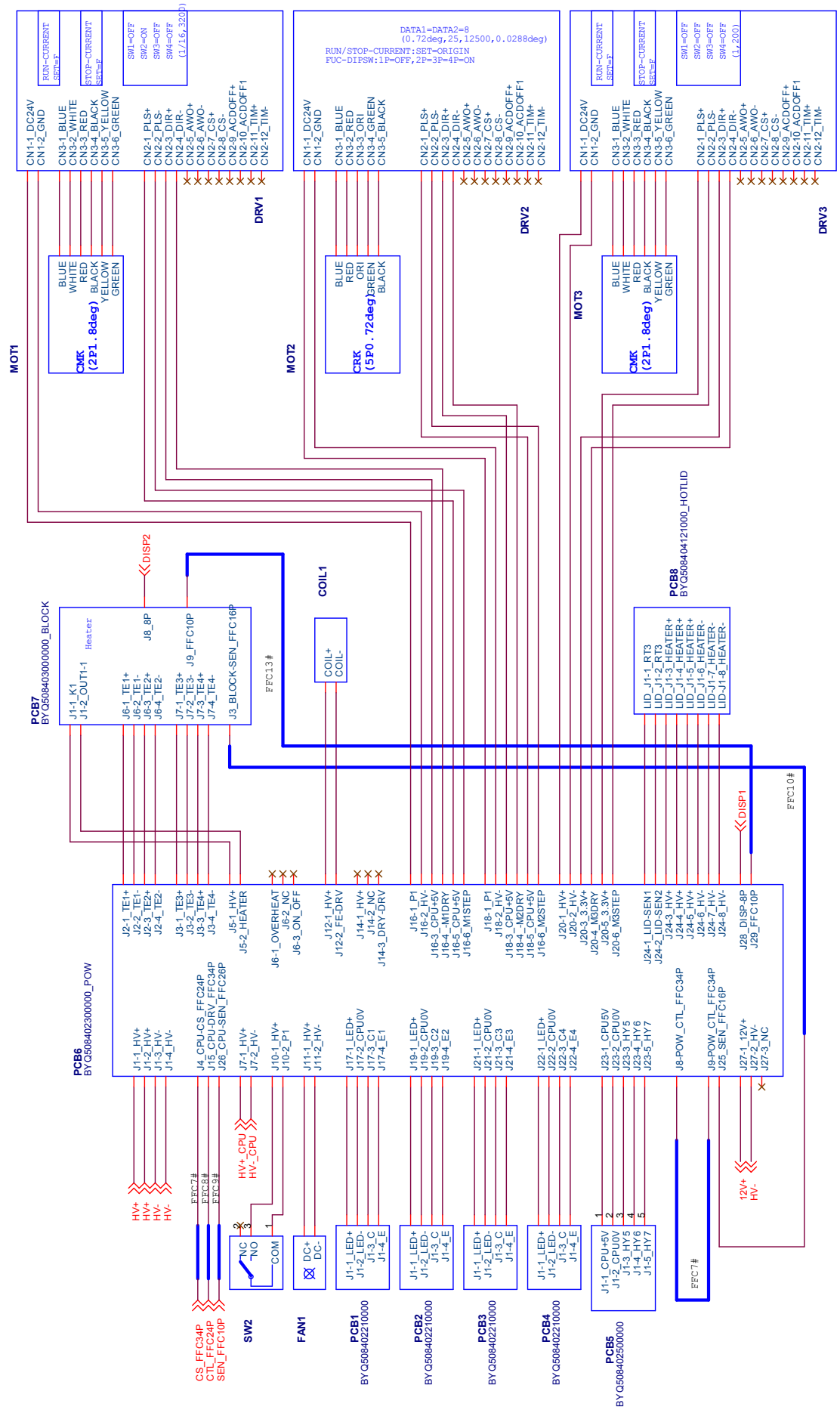
8	The module fails to heat and refrigerate.	Inside of instrument is damaged	Contact the supplier or manufacturer
		The refrigerating sheet is damaged	
		During hot-lid heating-up	Waiting until hot-lid temperature comes to target value. When stopping running, module temperature holds down 30°C automatically.
9	Abnormal temperature or fluorescence curve: straight line or lose of partial data	The running program is infected by virus	After virus-killing re-install application software.
		Computer configuration fails to meet requirements or the setup of communication port is unreasonable.	Configurating as per require ments
10	Yellow lamp on panel lights on	The module is not fully pushed in and the optic coupler fails to detect the module	In case of failure after re-pushing in, contact the supplier or manufacturer
11	The hot-lid is impossible to heat	Thermal-sensitive fuse is damaged	Contact the supplier or manufacturer
		Loose plug-pieces	
		Heating elements of hot-lid is damaged	
		Temperature sensor of hot-lid is damaged	
12	Under no test tube state, the fluorescence value difference between wells increases or the background value is very high.	The test tube well or hot-lid is contaminated, or baseline******.b96 background parameters are mis-used.	Eliminating contamination Each instrument shall correspond to baseline96 document. After perennial use, offset would occur in the optical elements. In this case, contact the manufacturer to re-calibrate the background value.
13	Reagent evaporation	There is the matter with quality of test tube, whose sealing is not tight.	To select applicable consumptive material which has more tight capability.
14	Signal crosstalk among channels	Dye signal among channels exists crosstalk objectively.	You can measure by using “Crosstalk Measurement”, and save parameters to modify.

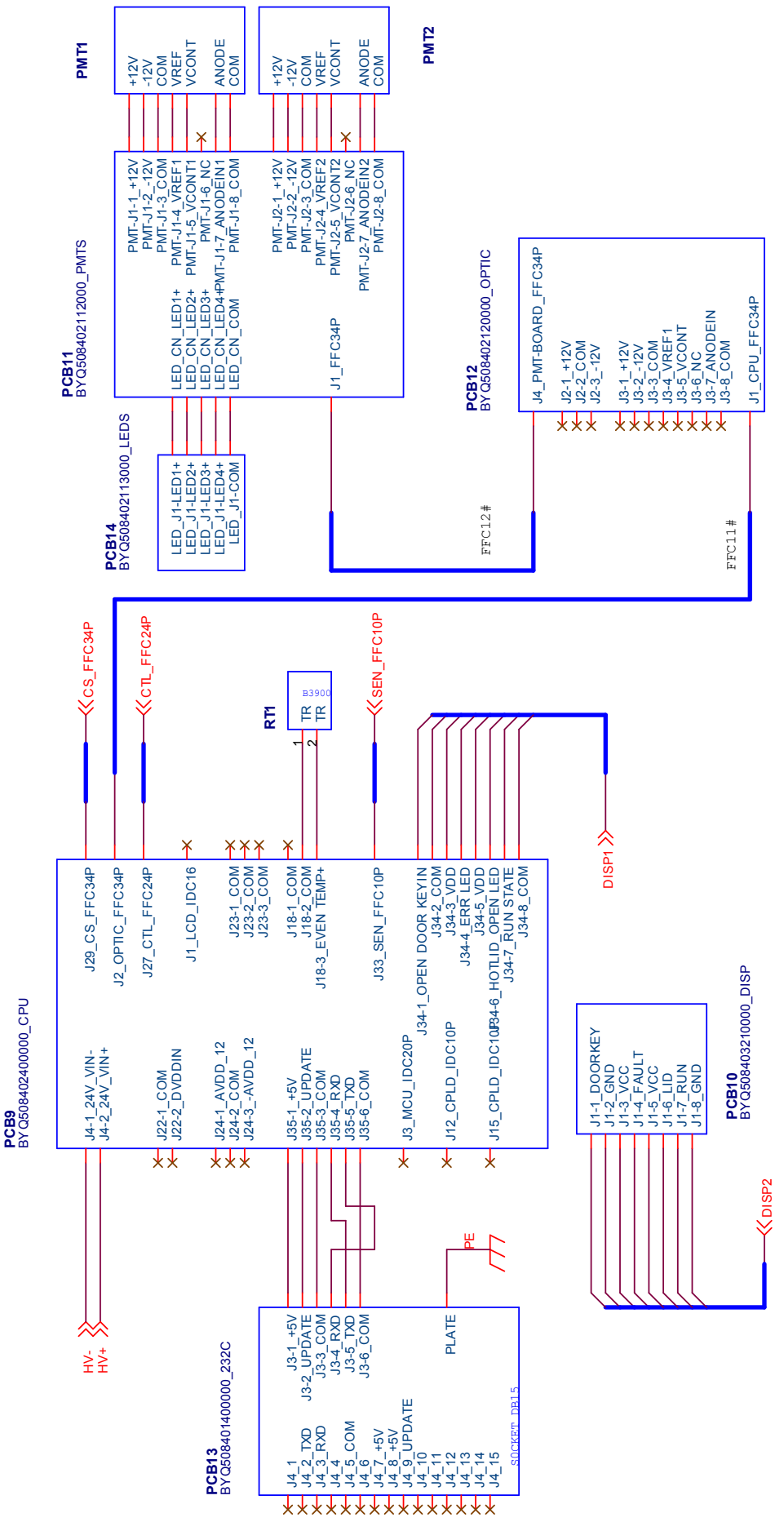
15	Fluorescence detection value -abnormal	Irradiation by external strong light	Close external light source
		During running of program, the hot-lid is opened	Close hot-lid (detection result unreliable)
		The photo-electric system is damaged	Contact the supplier or manufacturer

Caution: During the warranty period, arbitrary opening amplification instrument casing and inspection shall not be allowed. In case of above troubles requiring opening amplification instrument casing for inspection, please timely contact the supplier or manufacturer.

Appendix: LineGene 9600 series wiring




MOT1
MOT2
MOT3
DRV1
DRV2
DRV3
CMK (2P1.8deg)
CRK (5P0.72deg)
BLUE
WHITE
RED
BLACK
YELLOW
GREEN
ORI
PCB7
BYQ508403000000_BLOCK
PCB6
BYQ508402300000_POW
PCB8
BYQ508404121000_HOTLID
PCB1
BYQ508402210000
PCB2
BYQ508402210000
PCB3
BYQ508402210000
PCB4
BYQ508402210000
PCB5
BYQ508402500000
COIL1
SW2
FAN1
DISP1
DISP2
FFC10#
FFC13#
FFC7#
FFC8#
FFC9#
CS_FFC34P
CTL_FFC24P
SEN_FFC10P
HV+_CPU
HV-_CPU
12V+
HV-


PMT1
+12V
-12V
COM
VREF
VCONT
ANODE
COM
PMT2
+12V
-12V
COM
VREF
VCONT
ANODE
COM
PCB11
BYQ508402112000_PMTS
PMT-J1-1_+12V
PMT-J1-2_-12V
PMT-J1-3_COM
PMT-J1-4_VREF1
PMT-J1-5_VCONT1
PMT-J1-6_NC
PMT-J1-7_ANODEIN1
PMT-J1-8_COM
LED_CN_LED1+
LED_CN_LED2+
LED_CN_LED3+
LED_CN_LED4+
LED_CN_COM
J1_FFC34P
PMT-J2-1_+12V
PMT-J2-2_-12V
PMT-J2-3_COM
PMT-J2-4_VREF2
PMT-J2-5_VCONT2
PMT-J2-6_NC
PMT-J2-7_ANODEIN2
PMT-J2-8_COM
PCB14
BYQ508402113000_LEDS
LED_J1-LED1+
LED_J1-LED2+
LED_J1-LED3+
LED_J1-LED4+
LED_J1-COM
PCB12
BYQ508402120000_OPTIC
J4_PMT-BOARD_FFC34P
J2-1_+12V
J2-2_COM
J2-3_-12V
J3-1_+12V
J3-2_-12V
J3-3_COM
J3-4_VREF1
J3-5_VCONT
J3-6_NC
J3-7_ANODEIN
J3-8_COM
J1_CPU_FFC34P
FFC12#
FFC11#
CS_FFC34P
CTL_FFC24P
SEN_FFC10P
RT1
B3900
TR
TR
DISP1
PCB9
BYQ508402400000_CPU
J4-1_24V_VIN-
J4-2_24V_VIN+
J29_CS_FFC34P
J2_OPTIC_FFC34P
J27_CTL_FFC24P
J1_LCD_IDC16
J23-1_COM
J23-2_COM
J23-3_COM
J18-1_COM
J18-2_COM
J18-3_EVEN TEMP+
J33_SEN_FFC10P
J34-1_OPEN DOOR KEYIN
J34-2_COM
J34-3_VDD
J34-4_ERR LED
J34-5_VDD
J34-6_HOTLID_OPEN LED
J34-7_RUN STATE
J34-8_COM
J22-1_COM
J22-2_DVDDIN
J24-1_AVDD_12
J24-2_COM
J24-3_AVDD_12
J35-1_+5V
J35-2_UPDATE
J35-3_COM
J35-4_RXD
J35-5_TXD
J35-6_COM
J3_MCU_IDC20P
J12_CPLD_IDC10P
J15_CPLD_IDC10P
PCB10
BYQ508403210000_DISP
J1-1_DOORKEY
J1-2_GND
J1-3_VCC
J1-4_FAULT
J1-5_VCC
J1-6_LID
J1-7_RUN
J1-8_GND
DISP2
HV-
HV+
PE
PCB13
BYQ508401400000_232C
J3-1_+5V
J3-2_UPDATE
J3-3_COM
J3-4_RXD
J3-5_TXD
J3-6_COM
PLATE
SOCKET_DB15
J4_1
J4_2_TXD
J4_3_RXD
J4_4
J4_5_COM
J4_6
J4_7_+5V
J4_8_+5V
J4_9_UPDATE
J4_10
J4_11
J4_12
J4_13
J4_14
J4_15

Note：

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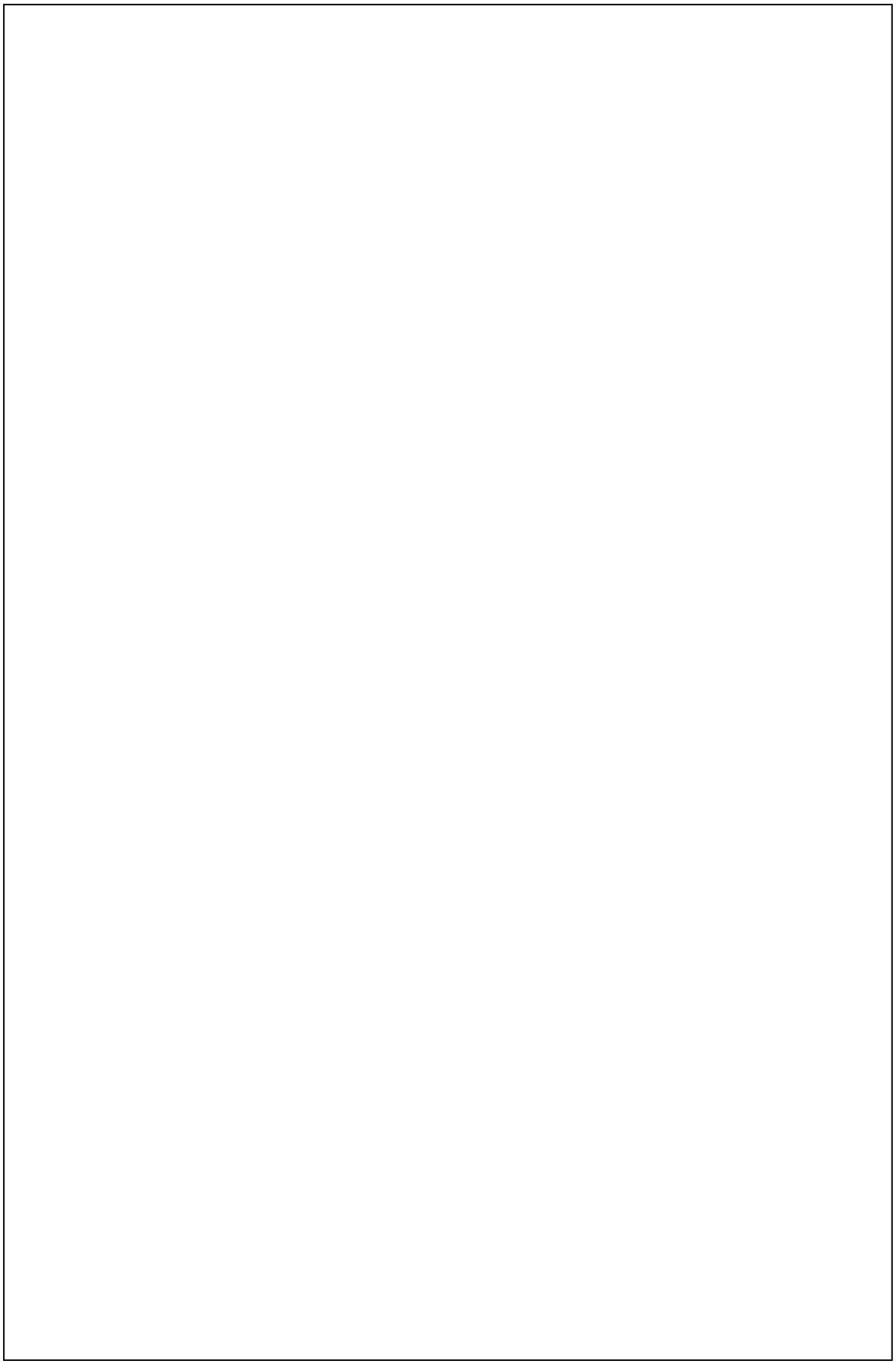

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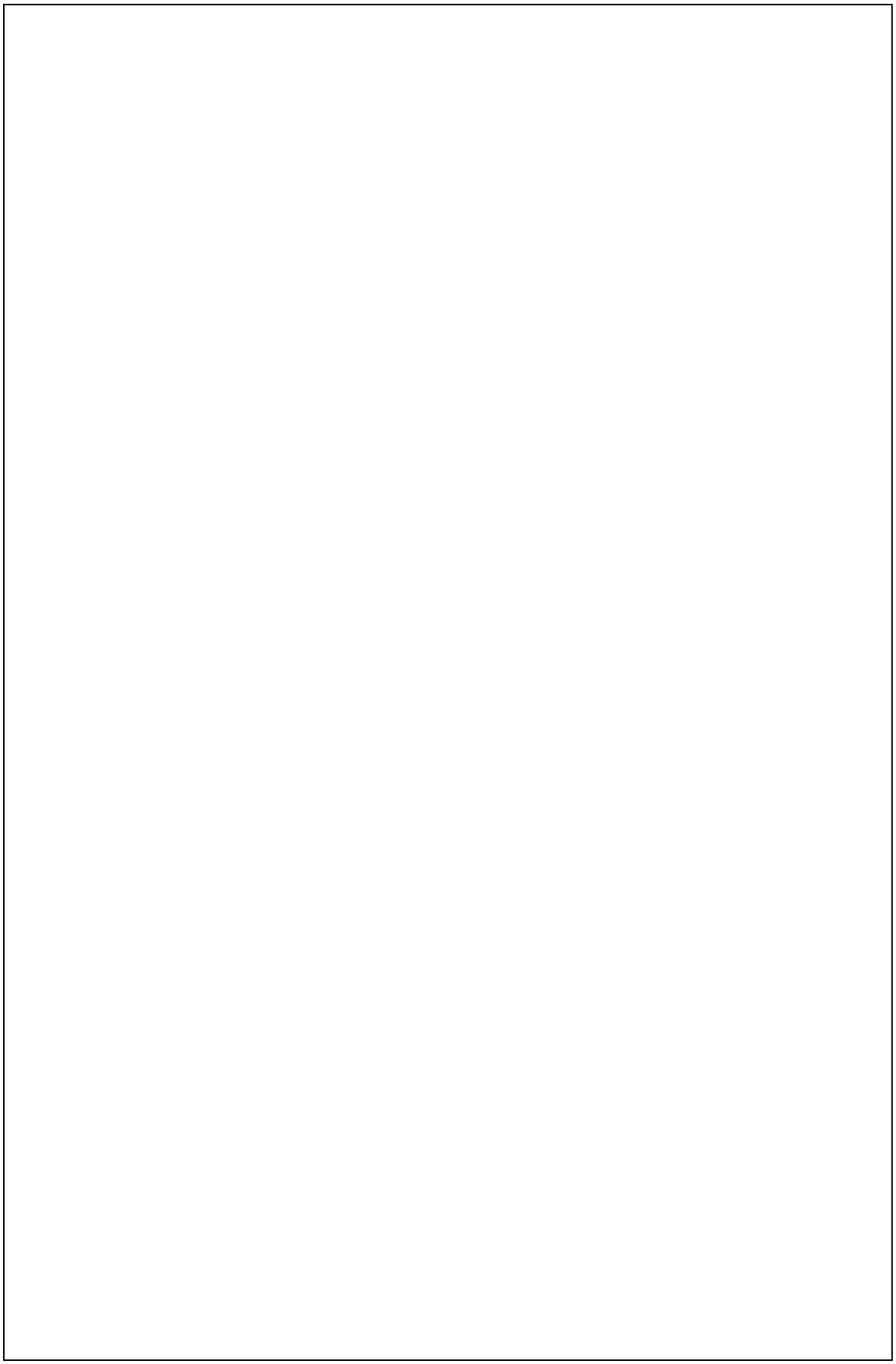
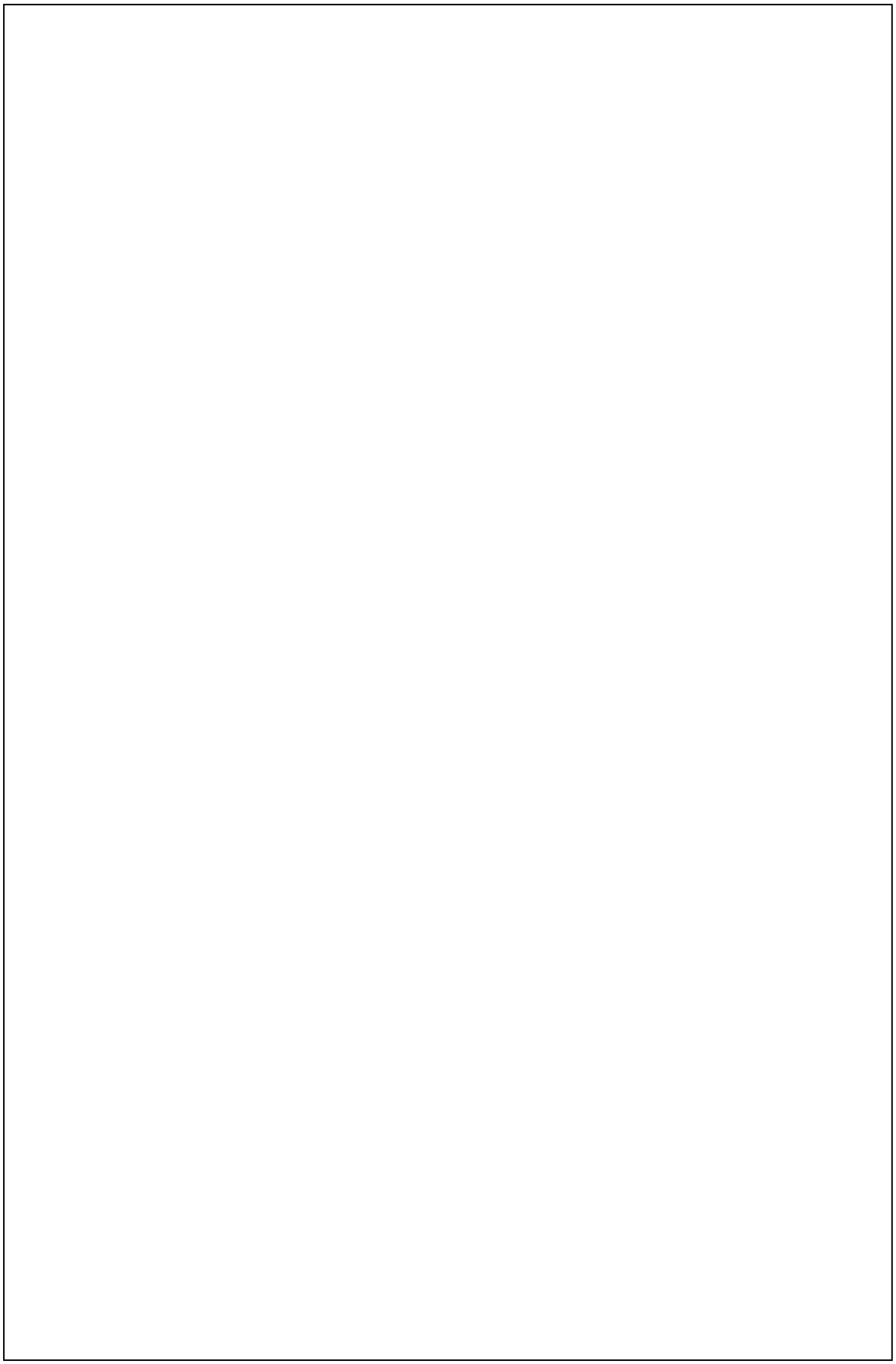


Note：



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